OVERSIGHT HEARING ON MIAMI VAMC CARDIAC UNIT

HEARING

BEFORE THE

SUBCOMMITTEE ON
HOSPITALS AND HEALTH CARE

OF THE

COMMITTEE ON VETERANS' AFFAIRS
HOUSE OF REPRESENTATIVES

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OVERSIGHT HEARING ON MIAMI VAMC CARDIAC UNIT

THURSDAY, MARCH 21, 1985

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:33 a.m., in room 334, Cannon House Office Building, Hon. Bob Edgar (chairman of the subcommittee) presiding.

Present: Representatives Edgar, Mica, Evans, Mollohan, Penny, Rowland of Georgia, Kanjorski, Robinson, Solomon, Johnson, and Rowland of Connecticut.

OPENING STATEMENT OF CHAIRMAN EDGAR

Mr. EDGAR. Good morning. The subcommittee will come to order.

We are honored today to have a group of distinguished physicians present. Two of the physicians have no formal connection with the Veterans' Administration and are here at the subcommittee's invitation to give us their perspective on the cardiac surgery program of the Veterans' Administration.

Dr. Michael DeBakey is a world-renowned cardiac surgeon who is the chancellor and chairman of the Department of Surgery at the Baylor College of Medicine. His face is familiar to the readers of Time and Newsweek. His credentials as a surgeon would take me at least half an hour to read, so I believe that we will just insert them in the record at this point and say that we welcome him to our hearing today and look forward to his testimony.

[The curriculum vitae of Dr. DeBakey appears at p. 53.]

Mr. EDGAR. Dr. Henry Bahnson is also with us this morning. He is the chairman of the Department of Surgery at the University of Pittsburgh Medical Center. I guess we have all heard about how Pittsburgh was recently named the most desirable city in which to live in the United States. Without opening up the debate, I would just like to note that the University of Pittsburgh makes a very important contribution to the quality of life in Pittsburgh.

Later this afternoon I will get on an airplane and fly to Pittsburgh and spend about 24 hours there, so I'm going to test out whether or not it, in fact, is the No. 1 city to live in.

That medical center plays a vital role in making Pittsburgh the remarkable city that it is. This distinguished witness is an outstanding surgeon in his own right, having served as president of the American College of Surgeons and as president of the Ameri-

can Association of Thoracic Surgery. He is the recipient of numerous academic honors as well, and we will welcome him in a few moments.

Our hearing today concerns the quality of care being provided to veterans who reside in the Miami, FL area, and who receive care through the cardiac surgery program at the Miami VA Medical Center.

Due to extensive press reporting on the performance of the Miami VA Medical Center's cardiac surgery unit, Congressman Dan Mica, a member of our subcommittee, requested this oversight hearing. While it is unusual to have a hearing on such a subject, dealing with only one hospital, I believe it is appropriate for this subcommittee to address the topic in order to learn the facts firsthand. As I indicated earlier, there has been extensive media coverage of the quality of health care being provided at the Miami VA Medical Center, and we have the director of the cardiothoracic service at that facility, Dr. Joseph L. Lester, with us today.

Also joining us this morning are Dr. Gerald Kaiser, the chief of thoracic and cardiovascular surgery at the University of Miami Hospital, and Dr. Robert J. Myerberg, professor of medicine and physiology, and director of the Division of Cardiology, University of Miami School of Medicine, which is affiliated with the Miami VA Medical Center.

The subcommittee is aware of the importance of public confidence in the ability of the VA to provide the best medical care. It would appear that the Miami cardiac surgery program has the confidence and respect of the Chief Medical Director and the person who advises him on such matters.

It should also be noted that the Chief Medical Director of the Veterans' Administration, Dr. John Ditzler, and his principal advisor on surgical matters, Dr. Robert Laning, have been invited to testify this morning. We welcome them and hope they will forgive me for not reciting their honors and awards as well as the others.

As I said, we are here to learn the facts surrounding the Chief Medical Director's decision to suspend and then reopen the cardiac surgical unit at the Miami VA Medical Center. We are also interested in learning how non-VA physicians such as Dr. DeBakey and others view the VA program: Is there sufficient monitoring of a surgeon's performance? What should the VA do when confronted with a situation where performance does not meet generally accepted levels of care? Are there steps that we, in the Congress, should take to ensure that the quality of care in VA medical centers is the very best that is available?

I have a number of questions for each of the witnesses, and I look forward to hearing from each of them as they speak.

Since our ranking Republican is not here this morning, I ask unanimous consent that his opening statement be made a part of the record at this time.

[The statement of Mr. Hammerschmidt follows:]

STATEMENT OF HON. JOHN PAUL HAMMERSCHMIDT, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ARKANSAS

We are here today to receive testimony on the cardiac surgical unit at the VA Medical Center in Miami, Florida. There has been an unfortunate public controversy about the quality of medical care at that facility.

Has the mortality rate been too high? Have there been problems with some of the staff? If so, have corrective measures been taken and are they effective? These are very serious questions that require definite and reassuring answers.

The VA has been investigating the situation. Hopefully, it will be able to tell us that all is now well at the Miami facility.

Mr. Chairman, it is absolutely necessary that when veterans come to the VA for heart surgery, they can have confidence that the VA is ready to serve them in a highly competent manner. Situations should not be allowed to develop where veterans who desperately need heart care are afraid to have it in a VA hospital because conditions give rise to adverse publicity about treatment they might receive.

If the Miami program is a good one, as we hope and trust it is, let's get the facts out right away, so that any fears of veterans that may exist will be quieted. If improvements are called for, let's be certain there is no delay in making them. Let candor be the watchword, so that the VA can continue to meet its commitment to providing our veterans with the very highest quality medical care.

Thank you, Mr. Chairman.

Mr. EDGAR. Are there any other opening statements that anyone would like to make? Dr. Rowland.

Dr. ROWLAND of Georgia. Thank you very much, Mr. Chairman.

I would like to take this opportunity to welcome Dr. DeBakey here and other colleagues in the medical profession. I had an opportunity to talk with Dr. DeBakey just a few minutes before the hearing started and learned that he knows a very good friend of mine who was one of the original researchers in vascular surgery from Atlanta, Dr. Harold Harrison. Dr. Harrison and I both came from Wrightsville, GA, and we also have another person of some note from there, Herschel Walker. So I don't want to open the debate with you, Mr. Chairman, but I do want to say that while Wrightsville is not comparable to Pittsburgh, we are proud of Wrightsville, GA and the people who came from there.

Thank you very much, Dr. DeBakey, for being here today.

Mr. EDGAR. Just remember where Dan Marino came from, and some of the other great quarterbacks from Pittsburgh [laughter]. So we do have a few football players who do come from Pittsburgh.

Dr. ROWLAND of Georgia. I certainly understand that, yes.

Mr. EDGAR. Dr. DeBakey, we are very pleased to have you here this morning. We look forward to your statement and your testimony. The full extent of your text will be made a part of the record and we ask you to proceed at this time.

STATEMENT OF MICHAEL E. DeBAKEY, M.D., CHANCELLOR AND CHAIRMAN OF THE DEPARTMENT OF SURGERY, BAYLOR COLLEGE OF MEDICINE, HOUSTON, TX

Dr. DEBAKEY. Thank you very much, Mr. Chairman, and members of the subcommittee. I deeply appreciate the opportunity of being with you today at this hearing. I hope you will forgive my voice. I have just been recovering from a bout of laryngitis and that's why I'm a little bit hoarse. I hope, however, you can hear what I'm saying.

I appreciate also your willingness to accept my statement for the record, since I am not going to read it. There are a few remarks I would like to make, and then perhaps, Mr. Chairman, you and the

members of the committee may have some questions you would like to ask.

First, let me say that I have had a deep and abiding interest in the Veterans' Administration for a long time. It actually began during World War II when I was assigned to the Surgeon General's Office and had the opportunity to develop a program which has continued in the VA system relating to research and the investigation, particularly on veterans who were in World War II and were followed for various reasons to determine the natural course of certain conditions that they may have developed during that time.

This has been expanded by the VA into, I think, one of the best research programs we have in this country. And this is evident also in the clinical research programs that the VA system has provided in a number of other areas, including the one we are concerned with today, the cardiovascular or cardiac surgery program. They were among the first to establish a collaborative program involving some 13 VA hospitals to compare the use of medical and surgical treatment in coronary artery disease.

Although I made some critical remarks about that in the early days, I want to say that it is a good program and that we now have followups from that program extending over 11 years that have provided some very useful information to all of us.

So, in general, I think the VA system has, in addition to providing good medical care for veterans, has added to our total sum of knowledge in the medical field by these types of activities—what we call clinical investigations.

The main thrust of my remarks is concerned with the evaluation of cardiac surgery—and these remarks are applicable to other fields, but specifically we're discussing cardiac surgery here. There is a procedure by which the standards in the field can be properly evaluated in any given institution. The VA system has perhaps one of the best procedures that is available, by which the quality of care being given to veteran patients is monitored and evaluated. In general, however, you should try to understand the process by which evaluation is made in a given institution.

Most institutions have two categories: the informal peer review system, and the formal peer review system. The formal peer review system is designated usually as a committee appointed for that purpose by the institution. The members are charged with the evaluation of the quality of standards being provided patients.

The informal process, in some respects, may be even more important, because it involves the members of the team. It is misleading to believe, as some would have you believe, and as sometimes is portrayed by the media, that the surgeon has the sole responsibility for making the decision. Usually, and certainly in most institutions, the decision is not made by a single individual. It is often made by a team, the surgeon being a member of that team. And since the team must work together in implementing whatever decision is made—whether it is medical or surgical treatment—they have a chance, in a sense, to evaluate each other in the manner in which they function.

If any member of that team, whether it is the medical member or the nonmedical member—because there are nonmedical members of the team as well—is not adequately contributing to the

team's highest standards, the team, as a whole, will find ways of getting rid of that nonfunctioning member, because the survival of that team is dependent on the highest standards of work. So the whole team is dependent upon the links in that team, and any weak link is going to affect the whole team. The informal process therefore often works as effectively, and sometimes more effectively, than the formal process.

I should now like to discuss the reliance upon statistical data. There is a tendency to rely heavily on a single statement about the mortality or morbidity rates without recognizing that doing this can often be quite misleading. For example, a mortality rate of 1 or 2 percent may suggest that the standards in that institution are good, when it may also mean that in the selection of patients, those considered high risks were eliminated completely or were sent elsewhere and, therefore were excluded from the statistics and in some respects, may mean that patients in that category are being denied proper treatment.

I can speak from my own experience in telling you that I personally see a high portion of high-risk patients who are referred to me who have been eliminated from statistical consideration in other institutions. We have to absorb those in our own institution if we are to give these patients the potential benefit of treatment, even though they are high risks.

Obviously, we explain the risk to the patient, and we often have to tell them that the risk of operation is quite high in their particular case—perhaps 10, 15, or 20 percent, as an estimated risk. We also explain to them the benefit of surgical treatment, and the patients then make the decision on the basis of what we call informed consent. But if one simply refuses to accept a high-risk patient, then that patient must either go elsewhere or is denied the potentiality of treatment. One therefore can't use these naked statistics as the sole criterion for determining whether the quality of work is adequate or inadequate.

The other thing you must remember with regard to these statistics is that other factors besides the heart determine the risk to the patient. Most of these patients are in the older age group, and their coronary disease is caused by arteriosclerosis or atherosclerosis.

A certain proportion of patients with arteriosclerosis or atherosclerosis will have disease in other arterial beds of the body. In fact, we have just recently published a report in the Annals of Surgery an analysis of about 13,000 of our cases in which we showed the relative incidence of atherosclerosis in the different arterial beds, including the coronary arterial bed, the carotid arterial bed—the arteries supplying blood to the brain—the arterial bed in the legs, and the arteries supplying the kidneys, liver, and gastrointestinal tract. There is a certain mix of patients with these various categories.

In our own experience, about 5 to 7 percent of patients with coronary disease have associated disease in other arterial beds of the body. This association adds to the risk of the operation because often these patients will have to have operations on, for example, the carotid artery as well as the coronary arteries.

In any given mortality statistic, therefore, one must understand that a number of factors may contribute to that figure. To make

comparisons between one institution and another, or one series of cases and another, without knowing all these factors that participate in the mix of cases, can result in misleading conclusions.

Mr. Chairman, I think I will stop at this point and perhaps answer any questions that you might have.

[The statement of Dr. DeBakey appears at p. 58.]

Mr. EDGAR. Thank you very much for your very good statement. We do have a number of questions.

I want to indicate to my colleagues that our next witness also has an airplane to make and we do want to get to the heart of the issue relating to the Miami hospital, so I would urge my colleagues to operate under the 5-minute rule in their questioning.

I would like to yield to my colleague from Florida, Dan Mica, who urged us to hold these hearings, and I commend him for that. He has an opening statement that he would like to make at this time.

Mr. MICA. Thank you, Mr. Chairman.

Will we proceed into questions after the opening statement, or wait for the other witnesses?

Mr. EDGAR. We will proceed to question Dr. DeBakey and then go to the other witnesses.

Mr. MICA. Just for the opening statement, what I would like to make very clear here for the record—and, Dr. DeBakey, I am very honored to have you here. Your reputation is something we all admire and I look forward to asking you a few questions and get your opinions on this issue. But I just want to lay the stage for this issue.

Headlines throughout Florida blared an issue to the public that said, in effect, that the Miami hospital had double the mortality rate in the cardiac surgical care unit than any other VA hospital in the Nation. Now, subsequently there has been some questions about other VA hospitals and their mortality rate.

I was approached, as a senior member from the Florida delegation on the Veterans' Affairs Committee, to say this is what the allegations are; what are you going to do about it. My response consistently has been this: not to hold VA to blame without evidence, but to say, in effect, if the allegations are correct, we want to stop it, we want to change it, we want to have a good facility there. If they are incorrect, we want to set the public record correct. We want to set the public straight and regain the confidence in the facility.

So that's the purpose here. This is not a witch hunt. This is not intended in any way to go after the VA or any particular individual. I was somewhat dismayed to see some reports that some people thought either our VA Committee, the chairman or myself or others, somehow were trying to zero in on the VA as a problem we wanted to address. It came about that way and I think it is legitimate. Every member of this committee would, I think, agree with me, that if there's a problem, they want it corrected. If there isn't a problem, we want the public perception corrected. So I appreciate your being with us here today.

With that, do we have an opportunity now to get into some questions?

Mr. EDGAR. Mr. Chairman, I yield to you.

Mr. MICA. All right. Thank you.

First let me ask your professional opinion with regard to the Miami facility. It was closed down, and we were told there were problems. Are you aware of the problems, were you aware of why it was closed down? Do you agree with the decision to close it down, or did you agree with that decision, and do you agree with the decision to reopen it? Not only Miami, but let's just talk a moment to nationwide. Do you see any other problems that we should be aware of. You've looked at it now.

Dr. DEBAKEY. Mr. Mica, I have not had the opportunity to make a thorough study of the Miami situation. I have, however, read some of the reports which were sent to me, and I also read the statement made by the chief medical director. I understand that they sent a team down there to look at the situation. I happen to know the individuals they sent down there—one of them is going to testify here—three very capable and perhaps among the most distinguished surgeons in this country. So I have every confidence in their conclusions. They recommended reopening the hospital, and the chief medical director did reopen it on the basis of the investigation they made.

It seems to me that the process is what's important here, and that the process does work. I have confidence in the process that the VA has set up. In fact, the monitoring process which the VA has set up is one of the best in the country in monitoring the quality of work in any VA hospital.

Mr. MICA. Then what you're saying is you have not looked specifically at the statistics that caused the closing of the Miami facility?

Dr. DEBAKEY. That's correct, I haven't actually looked at the individual cases and the data.

Mr. MICA. Did you look specifically at the report that was written and the reopening was based on?

Dr. DEBAKEY. Right. I certainly agree with that.

Mr. MICA. You have no medical or professional fault with the report or with the reopening?

Dr. DEBAKEY. What I'm saying is I essentially agree with the process and the recommendations that were made for reopening.

Mr. MICA. One point that I'm concerned with—and I have a chart before me, and I understand legally I am not allowed to read these numbers and the locations around the country. But I look even in another facility in Florida that had what we think was a similar age population but had a lower death rate, a lower mortality rate.

If we are saying, in effect, that because they are treating older and sicker patients and that is the reason, but we see another facility in a very elderly populated area of Florida without that rate, would that cause a question in your mind?

Dr. DEBAKEY. It would cause a question in my mind, but I am saying essentially, Mr. Mica, that I believe the monitoring process that is set up within the VA for that purpose is quite adequate. I would want then to know what the investigation showed in the monitoring of the data that they have.

Mr. MICA. I see my time is up and I would like to continue questioning, but I will abide by the rules and rotate with my colleagues.

Mr. EDGAR. Dr. DeBakey, when you compare a private hospital with a VA hospital, and you're trying to provide quality of care in both facilities, are there differences in terms of the kinds of patients that are being served that might, in fact, change the statistical data relating to the surgical procedure—in this case, cardiac surgery?

Dr. DEBAKEY. Of course, there are. Just to illustrate the point, we have in Houston a VA hospital that has been closely associated with us from the start. We also have several private hospitals, one of which is the one I work in, the Methodist Hospital. The mix of patients in the VA is quite different from that in our private hospital, and it is quite different also in relation to the cardiac surgery that is performed.

For example, they have very, very few patients who are below, say, the age of 40 or 45 years, whereas we have quite a few patients that fall in that category, and in addition, we have quite a few female patients. These can make a difference in the statistics.

Second, to illustrate also this point, we have just recently submitted for publication an analysis of our cardiovascular surgical experience in a book to be published on medical and surgical treatment in the elderly. In analyzing the mortality rate, for example, we found a sharp change in the mortality rate in all categories of cardiovascular surgery on the patients beyond the age of 55 to 60 years. It will double, and then, from that point on, treble, and maybe become four or five times the mortality rate in patients below that age.

Mr. EDGAR. So you're suggesting there is almost an exponential growth when you get beyond the age of 55?

Dr. DEBAKEY. That's right, exactly. This is based on our own experience, where the mortality rate, for example, in cardiovascular cases in general is quite low, 1 or 2 percent below the age of, say, 50 years. When you get above that age, it rises rather sharply.

Mr. EDGAR. So not only do you have to measure the mix of patient population but the age of that patient population as well?

Dr. DEBAKEY. More than those two factors are involved. There is also a mix in the kinds of patients operated on, the factors that determine, for example, the mortality rate, which we know from experience.

For example, one criterion we use is called the ejection fraction. This reflects the function of the left ventricle, how well it is contracting and how well it is putting out blood from the left ventricle. If that ejection fraction is below, say, 30 percent, the mortality rate is much higher than if it is above that figure. If in a given population you have a high proportion of patients with ejection fractions below 30 percent, you can see that the mortality rate will be higher.

Thus, many factors go into determining what that mortality statistic may be. It is difficult to compare it with another figure without having knowledge of all these other factors.

Mr. EDGAR. If, in fact, we were going to understand as adequately as we can the problem that was addressed at Miami, would it, in your opinion, be best to take a selection of hospitals in the VA who have similar characteristics and compare them according to the cri-

teria that you have laid out and then determine whether or not the morbidity rates are out of sync with what is the norm?

Dr. DEBAKEY. That is one way to do it. But my conviction is that this is better left to the process that is established for that purpose within the VA because they have experts who are evaluating it. They have established a process which involves a committee in the Central Office that is going to review all the data every 6 months in every VA hospital. They should be able to assess in a manner whether or not these standards are being met.

Mr. EDGAR. Congressman Solomon.

Mr. SOLOMON. Mr. Chairman, I have a number of questions, but I know that we are pressed for time. I just want to ask unanimous consent to submit questions and perhaps save Dr. DeBakey some time.

Dr. DeBakey, we are certainly honored to have you here and we are grateful that you came to testify before us. Thank you.

Dr. DEBAKEY. Thank you.

Mr. EDGAR. Without objection, members will be permitted to ask questions for the record.

Congressman Penny.

Mr. PENNY. Thank you, Mr. Chairman.

We welcome you to the committee this morning, Dr. DeBakey. I may have some questions that I would like to submit to you and to others who are testifying. For the time being, however, I have a committee conflict and I have to run down to another meeting. So if it would be all right, I would like to yield my 5 minutes to the Congressman from Florida, Mr. Mica.

Mr. EDGAR. We will yield your 5 minutes and wish you well.

Mr. MICA. Thank you, Mr. Penny.

Dr. DeBakey, I think this is one of the key points here. You have confidence in the system, and I certainly don't want to question the system without adequate evidence. But obviously what happened was it took headlines to bring out a situation—or at least a situation that was alleged in the headlines—to be worse than the rest of the Nation. And now I have a new article that says that there are five other hospitals with twice the VA or more of the mortality rate.

Are you confident to the point that, if the system is in place, there would not be a way to abuse it, so that the individuals who are doing the checking aren't a part of the problem? Obviously, the allegation is this. The articles that came forth said there's a problem, and it appears—and this is not my allegation; the allegation is in the paper—that the VA itself did not have in place the mechanism to address this problem.

Are you confident that that mechanism is in place, or should there be an outside review team to check the work of the review team? Are you aware enough of the way the process works?

Dr. DEBAKEY. In the first place, let me say that some of the members of the review team that are outside the VA——

Mr. MICA. You don't have any questions about the integrity of the way it is set up?

Dr. DEBAKEY. As an illustration, one of the individuals who is going to be testifying, Dr. Bahnson, has been on the reviewing

team. I have absolute confidence in Dr. Bahnson. So I am not concerned about that aspect of it, no.

I am sure that as they review these other institutions they will look into the quality of the work that is being done and determine whether the kind of cases they are having to operate on is contributing to the higher death rate, or some other factors, that may be responsible for it.

Mr. MICA. I guess to summarize, then, are you saying, in your professional judgment, that what you know of the procedure is enough to keep its integrity and you don't have any questions about that.

Dr. DEBAKEY. No. You see, there is always a lag between the development of statistical data and the evaluation of that data in terms of the quality of work being done. Obviously, you won't know whether there is a higher mortality rate until the statistics are given to you, until they're available. So there is a lag in that regard.

But the process itself, I have confidence in.

Mr. MICA. OK.

I was not aware that you had not studied the previous situation or looked at the reports. For me it is somewhat frustrating because some of the questions that I value your judgment on I don't know as you can address.

But with regard to the allegations, are you aware of what the allegations were, that there was a double higher death rate and——

Dr. DEBAKEY. Yes.

Mr. EDGAR. Would the gentleman yield?

Mr. MICA. Yes.

Mr. EDGAR. Let me just state for the record that one of the reasons we asked Dr. DeBakey to be here today is to give his opinion, from his experience over the years, in terms of cardiac surgery generally, so that we would have some guidelines in which to really question and ask those witnesses who have specific knowledge of the Miami situation a little more accurately, the kinds of questions that you are raising. Dr. DeBakey has agreed to come and share those specifics.

We had not intended that he be an expert witness in evaluating the specific report. We are going to get to that in a few moments. I think that questions of Dr. DeBakey in terms of trying to figure out how we measure the quality of care at Miami is really the valued area he can help us with. I just wanted to clarify that for other members so that we understand our two first witnesses are to give us information about cardiac surgery and their experience in hospitals and their knowledge of the VA and its practices, and then we will focus specifically on the Miami project as soon as those witnesses are completed.

Mr. MICA. Thank you, Mr. Chairman. I must say, I did have a misunderstanding. I thought Dr. DeBakey would give us some specific comments on Miami, and we do value your opinion on general procedures.

I think, from what I have seen, I have not seen any evidence to indicate that there is any individual or any conspiracy or any problem within the VA to whitewash or cover up any of the situation in Miami or anyplace else. But what I wanted to do was bring to

your attention what the allegations were and ask you if you felt there was any basis in fact after having looked at the procedure.

Now, I also had understood you were in Maimi——

Dr. DEBAKEY. No.

Mr. MICA. You were not in Miami?

Dr. DEBAKEY. No, I went to Orlando.

Mr. MICA. I see. I thought you were looking at this particular problem.

Let me just ask this, then: What are the basic number of procedures that you feel would be necessary to maintain a quality unit, and have you looked at the VA proposal for centers of excellence?

Dr. DEBAKEY. Yes. In general, I think the figure that has been used within the VA is 100 per year. I'm not sure that that's an adequate figure.

Mr. MICA. How many do you do a year?

Dr. DEBAKEY. Well, about 2,000. But I don't think that should be used as a standard, either, because we have a very large service, extremely large, and that involves more than myself. It involves my whole surgical team.

Mr. MICA. Yes. I think maybe I just prejudiced the record.

What would be the norm in a private sector clinic? That is an astounding figure.

Dr. DEBAKEY. Anything from 150 to about 500 I would say would be an average. The VA has used the figure of 100. I am a little concerned that that may be a relatively small figure. But they are evaluating and they have a good monitoring group which I have confidence in. They are continuously evaluating and perhaps revising some of those criteria to help increase the standards.

Just as an example to show you how statistics can be misleading, as I said, in our own VA hospital in Houston, our procedure for coronary bypass, including associated operations like valve replacements and so on, we had a mortality rate in 1982 and 1983 of around 9 percent. We were very much concerned about that figure within our own group because we felt that was much higher than it was in our private institution.

This past year, 1984, it is a little over 2 percent, so you can see how the figure can change. We made very little in the way of change—a few small changes. But it was largely a matter of selection of patients in reducing that mortality rate.

Mr. MICA. I'll come back on that, but I see that my time again has expired. Thank you.

Mr. EDGAR. Dr. Rowland.

Dr. ROWLAND of Georgia. Thank you, Mr. Chairman.

You pointed out the danger in looking at statistics and choosing the groups that you do. I want to ask a more general question.

As our techniques become more sophisticated, more and more people are looking for some relief of the problems that they have in medical care. How are we going to make the decisions about who is going to get what in the VA? How are we going to make those decisions? What role will the VA play in reference to overall medical care in the country in making these decisions? How can the VA help in determining what we do with each individual person?

Dr. DEBAKEY. I hope the VA can constitute an important force in providing high quality medical care to the veterans. I think it is

extremely important that the VA is maintaining the highest standards of care, but also providing care that includes the newest knowledge available along with the newest types of facilities and equipment available. Medicine is advancing constantly not only from the standpoint of our knowledge but also the kinds of equipment that is being used. The Veterans' Administration must maintain those quality standards if it is going to provide veterans with the best available medical care based on available knowledge.

I think it is extremely important that it is supported to that extent. It is an important force in medicine.

Dr. ROWLAND of Georgia. Do you feel the VA is doing a very good job in that respect at this point?

Dr. DEBAKEY. I do, very much so. You should remember that the VA is also contributing to the advance of knowledge through its research program. I would like to see their research program actually expanded because they have a great opportunity to do so, and they have a mechanism by which clinical investigation can be done on a collaborative basis even better than it can be done in the private sector. It has made significant contributions, in my opinion. It is therefore important to support the VA's general clinical program but also its research program.

Mr. EDGAR. Would the gentleman yield?

Dr. ROWLAND of Georgia. Yes, I will yield to the chairman.

Mr. EDGAR. The VA has a substantial research program, as you know. I wonder if you would comment about the relationship between teaching hospitals and the VA medical center. It has been our understanding that as the quality of VA health care is maintained, by closely trying VA hospitals to teaching hospitals. Would you agree with that?

Dr. DEBAKEY. Definitely yes. I participated in the very early days when that decision was being made. I happened to be in Washington at the time, in the Surgeon General's Office. I participated in it for nearly a year afterwards as a representative within the National Academy of Science in making a report for that purpose.

In addition to the knowledge it provides, the research program also attracts high-quality personnel. That is extremely important to the personnel that it is able to attract within the VA, and in many ways it is the quality of personnel that determines the quality of medical care within the VA.

Mr. EDGAR. Thank you. I yield back.

Dr. ROWLAND of Georgia. It certainly pleases me to hear you say that, to know that the VA is making a significant contribution to research and medical care that can actually be utilized in the population in general. I believe that's what you're saying.

Dr. DEBAKEY. Exactly.

Dr. ROWLAND of Georgia. Thank you very much.

Thank you, Mr. Chairman.

Mr. EDGAR. Thank you very much.

Mr. Mollohan.

Mr. MOLLOHAN. Thank you, Mr. Chairman. I have no questions. I yield my time to Mr. Mica.

Mr. EDGAR. Thank you.

Before Congressman Mica takes the mike again, Mrs. Johnson, do you have any questions at this time?

Mrs. JOHNSON. No, thank you.

Mr. EDGAR. Alright. I yield to my colleague, Mr. Mica.

Mr. MICA. Thank you.

Dr. DeBakey, I was interested in your closing comments in my last round of questions, where you said you went from 9 percent to 2 percent mortality rate without any changes——

Dr. DEBAKEY. No, I didn't say without any changes. I said with relatively minor changes.

Mr. MICA. Well, I think the point I was getting from your comments was that maybe you feel that mortality rates as a statistic aren't very indicative of whether or not there is a problem. Would that be a fair statement?

Dr. DEBAKEY. No, that isn't what I said, Mr. Mica. I want to be sure you understand what I said about mortality rates. I said that one should assess the mortality rate and use it, but it is important to understand what is involved in that statistic. That's the point.

Mr. MICA. Let me clarify my approach on this because I'm not trying to be a hostile questioner here.

I could very easily understand, for instance, if the VA comes up here after you and indicates that we did have a higher mortality rate, but we had older patients and they were sicker, and there were problems with these patients that maybe nobody else would operate on. In fact, that was probably one of the logical conclusions that immediately came to mind if, indeed, there wasn't a major problem with the physician's ability or physician's procedures.

Dr. DEBAKEY. Right.

Mr. MICA. The point is, you would agree with that?

Dr. DEBAKEY. Yes, I agree with that. One should certainly use the mortality rate in assessing the quality of care, but my point is that one should also try to determine what is involved in that mortality rate.

Mr. MICA. One other question. I understand you are pressed for time, so I will try not to use my full five minutes.

But there is a national review going on of all of the cardiac surgical care units.

Dr. DEBAKEY. Yes.

Mr. MICA. Are you participating in that?

Dr. DEBAKEY. It depends upon what you mean by a national review. We are participating in certain aspects of it, but not in all of it.

Every institution like ours that has a large cardiovascular surgical program is participating by presenting its material, analyzing its experiences, and presenting it at meetings and in publications. That constitutes assessment of the overall situation from every insitution. So there is a continuous interchange of information and data that helps to develop a consensus about the various aspects of the problem.

Mr. MICA. OK. I will ask the VA a little bit about that review. Again, not to try to focus specifically on Miami—and I know we're being rushed here for time—but I just want to make this clear.

You read the report of the panel that reviewed the Miami facility and you feel that it is a valid report——

Dr. DEBAKEY. Yes.

Mr. MICA [continuing]. It has basic integrity and that there are not problems or should not be problems now at the Miami facility?

Dr. DEBAKEY. Yes, I agree with the report and with the recommendation to open it.

Mr. MICA. Thank you, Mr. Chairman.

Mr. EDGAR. Thank you.

Without objection, I would like to put in the record at this point two reports that look at the issue of mortality rates. Both of them I think are helpful to the discussion and I will share those with my colleagues.

[The referred to reports appear at pp. 64 and 71.]

Mr. EDGAR. Dr. DeBakey, just a couple of technical questions.

Would you explain what the term "graft patency" means?

Dr. DEBAKEY. Yes. In doing a coronary bypass operation, we use a graft. We say a graft, but actually, it is either an internal mammary artery or a vein, which is perhaps the most common graft that is used. These are veins taken from the legs to be used to bypass blockage in the coronary arteries. They are attached above to the ascending aorta and below to the coronary arteries beyond the point of blockage. That's why it is called a bypass. It is sort of a detour and bypasses the blood around the blocked artery.

Graft patency means that the graft is functioning and blood is not blocked from flowing through it. There are different statistics, depending on the analysis used at different institutions, as to the number of grafts that are patent at the end of 1 year, 2 years, 5 years, 10 years. We have published our own reports, and many other institutions have published their reports. Graft patency will range, depending on a number of factors, at the end of 5 to 10 years from perhaps 70 to 90 percent.

Mr. EDGAR. I have two final questions I would like to ask——

Dr. ROWLAND of Georgia. Mr. Chairman, would you yield and let me ask a question about graft patency?

Mr. EDGAR. I yield to the gentleman.

Dr. ROWLAND of Georgia. Do you know, or are there any statistics, to indicate any difference between the graft patencies done in VA hospitals and those done in the private sector?

Dr. DEBAKEY. There were differences in the early days of the experience, when the VA published its first report on the collaborative study. In our commentary on that report, we pointed out that the graft patency in their report was lower than the graft patency in our own experience.

Since that time, I think the graft patency rate has come closer to the average that is reported in the private sector.

Dr. ROWLAND of Georgia. Do you know if there would have been any difference between the patients in the VA study statistically and those in the private sector that would have caused a lower graft patency in the VA sector initially?

Dr. DEBAKEY. At that time, no, I don't think so.

Dr. ROWLAND of Georgia. Thank you very much.

Mr. EDGAR. Those were the reports that I am introducing into the record and the response to them, so we will share those with you as well.

Dr. ROWLAND of Georgia. Thank you, Mr. Chairman.

Mr. EDGAR. I would like to ask two final questions. The first question is to ask the question we basically asked you in reverse; that is, if you were going into a hosptial, whether it was a private hospital or VA facility, and you were going to evaluate a cardiac unit, what would be the pieces of that evaluation that would trouble you? What would you have to find that would disturb you if you evaluated that facility and what would be some of the things you would look for on the negative side, not on the positive side?

Dr. DEBAKEY. The first thing is whether that institution has a reasonably good reputation—in other words, whether its past performance in general is good. For example, I would have great confidence in an institution like the Mayo Clinic that has an established reputation.

Then, in particular, I would like to know what the general experience of that institution is, what experience the staff has had, and the results of their experience.

That brings up the question of informed consent. In general, patients should be told when they are admitted to an institution for a particular condition about the experience in that institution with that condition, and what are the relative risks. We do that in dealing with every patient we see. We tell them exactly what we think is the relative risk in their case based upon the experience we've had.

Mr. EDGAR. My final question is, how do you, as a physician, judge another physician's competency?

Dr. DEBAKEY. If we don't know him personally, we tend to judge him by his publications, the reports he has provided, the quality of those reports, the way he analyzes the data, the way he draws conclusions based on the data, and so on. We get a pretty good idea of the competency of the individual on that basis.

If we know them personally, we judge their competence on an assessment of their relative judgment, the amount of experience they have, their technical competence, how well they do what they do, and their integrity.

Mr. EDGAR. Thank you very much.

Are there any other questions of Dr. DeBakey? I yield to Mrs. Johnson.

Mrs. JOHNSON. Thank you very much.

About a year ago we had a report from a number of physicians, well known and eminent individuals, who voiced some really serious concern about the quality of care in VA institutions. It wasn't really a matter of incompetence of physicians or of malice of heart on anyone's part, but they did point to a number of management practices that compromised quality. For example, inefficiency in replacement of instruments, of sterilization processes, sterilization equipment and so on, that often caused delays in the middle of operations and things like that.

Now, I wonder if there are suggestions that you would make to this committee as to the kinds of things we ought to look at to either enhance or assure quality of care that has to do with the funding and management mechanism.

Dr. DEBAKEY. I am not sure that I know the report you are referring to. If they have been published, I haven't seen them.

Mr. EDGAR. If the gentleman would yield, it was a report from physicians dealing with the orthopaedic side of the VA medical system. It was one group of physicians' opinion about the VA procedures.

Dr. DEBAKEY. I'm not familiar with that. I can only speak about what I know in relation to at least some of the VA hospitals I have visited, particularly our own. I can specifically say in our own case, at the VA in Houston, that has not happened.

Mrs. JOHNSON. Thank you, Dr. DeBakey.

Mr. EDGAR. Thank you very much for your testimony. We wish you well. We are also the committee that has responsibility over replacing the Houston VA, but we didn't get into those discussions——

Dr. DEBAKEY. I would like very much to speak on behalf of that. [Laughter.]

Mr. EDGAR. I thought maybe you would. Thank you very much for your testimony.

Dr. DEBAKEY. Thank you.

Mr. EDGAR. Dr. Henry Bahnson, chairman, Department of Surgery, University of Pittsburgh Medical Center. Dr. Bahnson, we appreciate your attendance here and we thank you for coming and your patience. I don't know what time your airplane is, but——

Dr. BAHNSON. It's a little later.

Mr. EDGAR. The full text of your statement will be made a part of the record.

You have heard many of the questions. We have asked you here as an expert witness to give us your opinion. We really appreciate your taking the time and energy to be part of this discussion this morning. Following your statement, we will get specifically to the Miami VA.

STATEMENT OF HENRY BAHNSON, M.D., CHAIRMAN, DEPARTMENT OF SURGERY, UNIVERSITY OF PITTSBURGH MEDICAL CENTER

Dr. BAHNSON. Thank you, Chairman Edgar, and ladies and gentlemen. I appreciate your plug for our southwestern corner of the State. We had been hoping to keep that a secret.

I am here representing two other colleagues, Frank Spencer and Tom Ferguson. Dr. Spencer is chairman of the Department of Surgery at New York University, in New York City, and Dr. Ferguson is director of thoracic surgery at Washington University in St. Louis and the chief of thoracic surgery at Barnes Hospital.

To add a little more to the credentials of this group, I would say we are all practicing surgeons in the private sector. We all direct or have been involved with thoracic surgical training programs. We have all been members of the American Board of Thoracic Surgery, which is the accrediting organization in the country. One of the members has been chairman of that board. One of the members has been a member of the Residency Review Committee that reviews the performance of the training programs. All three of us have been president of at least two of the four thoracic or vascular surgical professional societies in the country. One is an editor of one of the two leading journals in thoracic and cardiovascular sur-

gery, and two of us have been regents of the 47,000-member American College of Surgeons, and one has been president.

We met at the request of the VA in the Central Office in Washington and reviewed much of the data that you have had presented to you. We later met in Miami with a site visit. We interviewed the members of the administration, the surgical service, the cardiology service, medicine, the nursing service and anesthesiology to name a few. We reviewed the history of the program, going back to 1972 when it came under its present leadership and direction from the medical school.

We much more carefully reviewed the performance in the last year, which we thought was much more pertinent in that during this time it has been under continuous and its present leadership, and we much more specifically reviewed the deaths that occurred during this time.

We attemped and did, I think, adequately evaluate the personnel, particularly the leaders of the program, by interviews with them. We inquired of those who had been associated with them in the past, in their training and in their subsequent performance. We reviewed the internal methods of review that the Miami VA hospital uses.

We compared the performance of that program with other VA programs in the country and we did our best to compare it with non-Government hospitals, both in Miami and in our own environments, examined their facilities, and we reviewed—although I must admit only very briefly—some of the adverse publicity that has been referred to that was published in the local news media.

This morning before the hearing I had the opportunity to read the report that Dr. Ditzler has made and to read the release in February to the public when he recommended the reopening of the program.

I believe and am confident that I speak for my other two colleagues in saying that we——

Mr. EDGAR. Would the gentleman yield? Without objection, I would like to insert at this point in the record the two reports that the gentleman has just mentioned. Without objection, it will be placed in the record.

The gentleman may continue.

[Dr. Ditzler's report and release appear at pp. 83 and 85.]

Dr. BAHNSON. I am confident that my two colleagues would agree with the report and recommendation of Dr. Ditzler. I have also had the opportunity to read the reports which will be given later of Dr. Kaiser, Dr. Lester and Dr. Myerburg, and I believe as far as we were involved with the facts of those presentations, I think our group would agree with that.

So I believe I will stop with that and try to answer any questions you may have.

Mr. EDGAR. Thank you very much. I apologize for not mentioning the fact that you headed the team that did review the specifics of the Miami facility. We are really pleased that you had the time to come and present your case.

I have a number of questions that I would like to ask, and I will first yield to my colleagues and then come back to my line of questioning.

I yield first to our colleague from Florida, Mr. Mica.

Mr. MICA. Doctor, do you think the facility should be open in Miami right now, no ifs, ands, or buts?

Dr. BAHNSON. That's the recommendation. Yes, I do.

Mr. MICA. Do you think it was closed on appropriate evidence, and what was the evidence?

Dr. BAHNSON. I was thinking when you asked Dr. DeBakey that question. If the Pitt Panthers and the Steelers knew during their games what they know Monday morning they wouldn't lose many games. I think that retrospective vision applies to this affair now.

I am not sure of all the facts and pressures that were on Dr. Ditzler when he recommended closure. I would say we heartily agree with his recommendation to reopen it.

Mr. MICA. You didn't make a judgment then as to whether or not there was a problem that would require the closing of the facility?

Dr. BAHNSON. It wasn't my judgment to make.

Mr. MICA. So you made the judgment, though, that it should be reopened?

Dr. BAHNSON. Yes.

Mr. MICA. And you see no problems there at this time?

Dr. BAHNSON. That's correct.

Mr. MICA. Have you made specific recommendations for changes?

Dr. BAHNSON. Yes.

Mr. MICA. Would you tell us what the major ones are? I have read your report.

Dr. BAHNSON. You know your rules better than I do. That's part of the report that we made, and I believe the members of the committee have the report available. I had understood the recommendations were sequestered—not sequestered, but confidential information.

Mr. MICA. All of those recommendations would be covered——

Mr. EDGAR. Would the gentleman yield at that point?

Mr. MICA. Let me ask the chairman. Are all of the recommendations——

Mr. EDGAR. As far as I'm concerned—and there is no armed guard that's going to carry you off—I think it is important for the public to know what the general recommendations are. I think the rule basically states that the specifics of the details as to how you got to the recommendations and the basis of your report are clear. I think it is important for us here in this open hearing to hear as much of your recommendations that you deem you can share with us. There is no penalty for you or for members that I understand or can determine.

So in answer to the question of the gentleman from Florida, it would be helpful if we could for the record list out in as open a way as you feel appropriate——

Mr. MICA. Mr. Chairman, maybe I could offer a suggestion on this. I obviously have been an advocate for getting it all on the record.

But, Doctor, would you say there were any of your recommendations that were not put into effect?

Dr. BAHNSON. I am confident that all the recommendations were put into effect.

After Chairman Edgar's comments, there is nothing world-shaking about any of the recommendations, other than——

Mr. EDGAR. That's my point.

Dr. BAHNSON. The others have already been quite clearly made. They were such as have a more formal review weekly in conjunction with the staff from Jackson Memorial Hospital and Medical School. They are already doing that. That had already been implemented. The others are similar to that. There were recommendations made that were for the Director of the VA, to ask the VA there to do, but they really had nothing to do with opening or reopening the program.

Mr. MICA. You know, Mr. Chairman, I know we have some restrictions on this law, and——

Mr. EDGAR. Without objection, those restrictions are overruled.

Mr. MICA. Well, I want to be the last one to get into a situation where we're doing something that is inappropriate.

I will try to put it in this order: Would you say there was a problem; you addressed the problem and it's been corrected; or there was not a problem; these articles and these allegations were inappropriate; and the items you recommended, therefore, would enhance the program, but there really wasn't the concern that was indicated in the article?

You said you read the articles, didn't you?

Dr. BAHNSON. I said I read them briefly and not thoroughly.

Mr. Mica, I think most of the evidence that was used was evidence from a previous era. There had been problems with the VA, and the VA and the local authorities who had directed the program had taken actions in the past to try to correct those. I believe that was a hangover from earlier days and it was the earlier data that had been released to the press.

The performance that we found of the program in the past year was excellent. It was on that that we based the recommendation that the program be reopened.

Mr. MICA. The specific time period we're talking about would be from when to when?

Dr. BAHNSON. From January 1984 to December, when the program was closed.

Mr. MICA. And the mortality rates in that year, considering all the factors of the individuals involved, was acceptable?

Dr. BAHNSON. It was acceptable—well, to a surgeon, no mortality is acceptable. But, you know, it has to be in line with other programs. It has higher in some and we accept that also.

Dr. DeBakey talked about the fallaciousness of mortality data. One can juggle the mortality rate high or low, depending on what sort of patient you're operating upon.

I guess to elaborate a little bit upon that, the program in 1984 was improving. It became evident to the colleagues of Dr. Lester, who was conducting this program, that the results were good and more and more things were asked of him to try to perform. It is unfortunate, but once one has a couple of successes, your colleagues begin to think you can walk on water. You can't do that. They begin to offer you a patient that has 1 chance out of 5 or 10 that he might survive, or an 80-percent chance that he won't survive. But they think you might just have that 1 chance in 5 of get-

ting the patient through. That's the sort of thing that badly skews any sort of mortality figures.

Mr. MICA. Specifically, then, you're saying there was a problem before 1984, that it was corrected or was in the process of being corrected in 1984; that there is no problem; the recommendations that you made were just to enhance the program but not to correct what the allegations would infer, as some particular major problem in the system or in the unit?

Dr. BAHNSON. I think that's correct.

Mr. MICA. Mr. Chairman, I know my time is up——

Mr. EDGAR. Go ahead. We will yield the gentleman 5 additional minutes.

Mr. MICA. You indicated you reviewed the individual cases for 1984?

Dr. BAHNSON. Yes.

Mr. MICA. And you found no problems there?

Dr. BAHNSON. I don't think I have ever reviewed a mortality rate anywhere that you couldn't find something that you wish you had done differently, and that applies to our own figures we reviewed yesterday and the figures from Miami. But in terms of things that, had you been there at the time would things have been done differently, I think that is a correct statement. They are in line with other figures. Surgical care is not perfect.

Mr. MICA. Are there any major differences in the operation of the cardiac surgical care unit in Miami or any other VA hospital that you're aware of that are different than your operation or the private sector because of law, regulation, or VA rules?

Dr. BAHNSON. Well, that's a pretty broad question. I think——

Mr. MICA. Well, I'm not talking about little things. I mean major—let me try to define it a little more—any major differences that would result in the health and safety of the patient.

Dr. BAHNSON. I don't think there is anything that would affect the health and safety of the patient; no.

Mr. MICA. And you feel you have conducted a very adequate survey and that the integrity of each of the individuals was not in any way jeopardized? I will tell you publicly, obviously there were allegations in the paper that some had worked for the VA and, therefore, it may not have an unbiased approach. Others would say that the fact that they worked for the VA or that they worked for our Government should never be viewed in a negative light, and I understand that.

How would you respond to that?

Dr. BAHNSON. Well, I think all three of us are associated with the VA because VA hospitals in our home cities are university-affiliated programs. I think you will have a hard time finding academic leaders who are not in some way connected with the VA because I think it is good for the VA and it is certainly good for our academic programs.

I am down here—I guess maybe the VA is paying my expenses—they may not be. But in that sense, we worked as consultants when we went to Miami. It is true, however, that none of us are Government employees or got anything other than a consultant's fee or per diem or anything else from the VA. We are not employees of the VA. I honestly believe we were selected as consultants because

they knew we represented a totally different area from the VA, although obviously we know the VA people and work with them and try to cooperate with them.

Mr. MICA. The statement was made, I believe, in one of Dr. Ditzler's press releases that the Miami VA mortality rate in the cardiac surgical care unit was somewhat equal to other facilities in the Miami area, I guess inferring that the population which is older and possibly sicker in that area maybe would provide for or you would come to expect a higher mortality rate.

Did you compare the rates of the Miami unit with other units in the area?

Dr. BAHNSON. Yes, we did. The figures that were given to us, which are confidential but at least open to us, from the Jackson Memorial Hospital there, and also with other information which was confidential from two other leading hospitals in town, the mortality rate in the VA hospital was right in the middle of those four figures.

Mr. MICA. I don't want to press the time but let me just make this statement.

I came to this hearing with the express purpose of either making a decision that I see a problem and we need to address that problem, or I questioned the validity of your report, and I don't. Everything I have heard so far this morning does not indicate there's a problem. The newspaper articles indicate there was a problem.

In reviewing the newspaper articles versus what you have seen, do you see a discrepancy—possibly the reporter, either without medical knowledge, or the information the way it was presented—that it presented a case that wasn't sustained or shouldn't be sustained, or do you see any validity to anything that was in the articles that you read?

Dr. BAHNSON. I think there is validity in the goals. The goal of newspaper articles is to inform the people, but probably more important, it is to sell newspapers. Our goal was to try to find out the safety of the program. I think there was some validity, and I mentioned that I think they were using data from a previous era. They were comparing mortality rates without weighing them the way I and my colleagues attempted to do, for reasons that have already been mentioned earlier.

Mr. MICA. I would like that to be made very clear, according to you and Dr. DeBakey, that to weigh mortality rates as a raw statistic without the accompanying data on the individuals, from what I'm hearing today, is probably in error; is that correct?

Dr. BAHNSON. Yes.

Mr. MICA. I see my time is up.

Mr. EDGAR. Thank you. Dr. Rowland.

Dr. ROWLAND of Georgia. Let me ask a question. I am not familiar at all with the articles that were in the Miami paper, but was the information presented in the Miami paper based on something prior to January 1984?

Dr. BAHNSON. Yes, the articles that I saw were. I am not sure I read everything, but the articles that I saw were.

Dr. ROWLAND of Georgia. As of January 1984, in reviewing the hospital, you found that it was in good shape so far as the investigation was concerned?

Dr. BAHNSON. As far as the facility was concerned, yes.

Dr. ROWLAND of Georgia. It causes one to wonder about the reporting of the information, and your statement that maybe a newspaper is in the business to sell newspapers might have had something to do with the furor that was created.

Dr. BAHNSON. I think that's a significant factor in news media everywhere, is it not? I'm not sure what that has to do with this, but that's my own opinion.

Dr. ROWLAND of Georgia. I think it has to do with what Mr. Mica was concerned about maybe.

Thank you, Mr. Chairman.

Mr. EDGAR. Thank you.

Mrs. Johnson, do you have any questions?

Mrs. JOHNSON. No.

Mr. EDGAR. I really appreciate your testimony, and I do have several questions.

First let me get back to what I tried to do earlier in terms of your report. We are in an area that is difficult for everyone because we respect your ability to go down and do a site visit, to take the data that was provided, and in in a spirit of confidentiality make your recommendations to Dr. Ditzler. There is an important opportunity I think for us to respect that process, and I want to talk about that in a minute.

These hearings are public hearings, and the reason that I tried earlier on with Congressman Mica to encourage you to make comments about your recommendations was that it seems to me there's a two-track parallel system that we can use, and that is the private documentation that you gave to Dr. Ditzler as your recommendations and now the opportunity, based on the information you know, to make a public statement in a public record. I want to thank you for making that public statement in a public record and assure the committee that we want to continue a process that will allow experts like yourself to review problems within the VA. There are problems within the VA; there are problems within any medical system as large as the VA system. We need to be able to get competent persons like yourself to go and review those problem areas and come back with your list of recommendations.

Let me ask you a specific question. Are there any steps which the VA should take now in relationship to your recommendations that either speak to your recommendations or go beyond those recommendations that should be implemented either at the Miami hospital or other hospitals that you would make at this point?

Dr. BAHNSON. I don't know about other hospitals. I am really only concerned with the Miami VA.

Mr. EDGAR. I guess when I used the word "other" hospitals I was meaning in terms of, from what you learned in Miami, are there any recommendations that you would have that would be important to Miami and also could be important to other hospitals?

Dr. BAHNSON. I would think so.

Mr. EDGAR. Are there any recommendations that you would make specifically just for the Miami facility that are not being followed through at this time?

Dr. BAHNSON. No.

Mr. EDGAR. Let me ask you a couple of questions about the process. Are there any tools that your team needed that were not made available to you?

Dr. BAHNSON. No, I don't think so. What we requested was readily available and freely supplied.

Mr. EDGAR. What did you use for clerical help and staff help in order to make your review?

Dr. BAHNSON. Well, much of the data was gotten together by the VA both here in Washington for the review and there in Miami. The clerical help after that was my secretary.

Mr. EDGAR. Suppose you had gone to the Miami facility and found gross errors in judgment, or problems with existing staff, and you brought back those recommendations to the VA; are you confident that the VA would have followed those recommendations as aggressively as they followed the recommendations that you made?

Dr. BAHNSON. That's hard to say. I have a lot of confidence in the VA. Yes, I think that confidence would be reflected by expecting and believing they would do what they thought best. If they disagreed with our recommendation, I would think that would be their right to get other data or get other opinions.

I would point out that they already had a review of the Miami program the preceding spring, less than a year ago. There was a review by VA consultants and their review similarly spoke to the excellence of the program that was underway at that time in the spring of 1984.

Mr. EDGAR. Based on your knowledge of the Miami facility, do you recommend to this committee any additional steps that we should take to study the problem at Miami, or do you think the recommendations and the follow through of those recommendations are sufficient?

Dr. BAHNSON. I think they are sufficient.

Mr. MICA. Would the gentleman yield?

Mr. EDGAR. I yield to the gentleman.

Mr. MICA. Just a quick point.

Doctor, have you participated in other review teams?

Dr. BAHNSON. Other review teams? Yes, many of them.

Mr. MICA. Have you come back and reported negative findings?

Dr. BAHNSON. Yes.

Mr. MICA. And you had no compunction to come back and do that here?

Dr. BAHNSON. No, absolutely not. I think that's why we were asked.

Mr. MICA. And you felt that when you reported the negative ones that they followed through on those, also?

Dr. BAHNSON. Yes.

Mr. MICA. And on this particular one you didn't report any major negative findings?

Dr. BAHNSON. That's correct.

Mr. MICA. Thank you, Mr. Chairman.

Mr. EDGAR. Doctor, there has been some criticism of the Veterans' Administration for allowing the proliferation of cardiac surgery units where there are too few patients to sustain the program.

Do you believe there is validity to this criticism?

Dr. BAHNSON. Yes, I think a certain volume of work is needed.

Mr. EDGAR. What would you recommend in terms of the volume?

Dr. BAHNSON. The VA's number of 100 is probably a good ballpark figure. I think the situation in the VA in Miami, though, is different. It is worth pointing out that the program there is part of an integrated program with the university, of which the hospital is just across the street. The team that works with the VA is also working every day of the week at the other adjacent hospital.

Mr. EDGAR. So we should add the VA patients with the other patients if it's the same team; is that what you're suggesting?

Dr. BAHNSON. Yes. And that is certainly true in our environment and many others. One of the recommendations was that the VA should in this particular environment—it was published by Dr. Ditzler, I believe—that they should not be required to maintain the 100 case per year level. It is very likely that that program will have a higher volume than that. In fact, they were working at a higher volume than that when it was discontinued. But that is not as necessary in that program as it might be in Clarksburg, WV, or someplace that is not much more closely affiliated with a close-by teaching hospital.

Mr. EDGAR. Could you describe for us the age issue as it relates to the Miami hospital and the kind of patient mix that the physicians are using in terms of their cardiac operations?

Dr. BAHNSON. The importance of age?

Mr. EDGAR. I would like to hear your comment on age as an issue in terms of determining the mortality statistics, but also what did you find in the Miami facility in terms of the characteristics of patients, one of which is the characteristic of age?

Dr. BAHNSON. Well, age certainly is important. As has already been mentioned this morning, there is a quite striking increase in mortality and some degree of exponential increase certainly past 65, and even earlier than that.

In regard to the Miami patients, they were, in general, sicker ones and older ones. We didn't statistically compare that, but it is a known fact to anyone who has connections with the VA—it is certainly true in our own program at home.

It is maybe sort of a flippant comment that the profession uses, but it is easy to take care of patients who can jog to DeBakey's program or even our program or the Cleveland Clinic, at least walk there, but sometimes jog in and be operated upon. There aren't many patients of that type that are treated in the VA.

Mr. EDGAR. Do you believe that if the Miami Veterans Hospital were to treat a broader mix of patients that their statistics would have been lower?

Dr. BAHNSON. If they were younger and economically and otherwise better protected—all of which does have an effect on health—the mortality rate I think certainly would have been lower.

I think it is also important to emphasize, as I mentioned earlier, that as this program became active and it was realized very quickly that there had been a virtual complete turnabout in terms of results, there were more and more difficult patients referred to them, irrespective of age and these other criteria. They were patients that clearly would not survive without some last ditch effort. Some of the deaths were due to that.

Mr. EDGAR. I want to ask you a question about your experience. We have asked a number of questions this morning on age. I spent some time as a hospital chaplain in the city of Philadelphia and at that time we had two hospitals side-by-side. One was a city hospital, the Philadelphia General Hospital, and the other was the University of Pennsylvania Hospital, a teaching hospital. I noted as a chaplain that the patient's income at the University of Pennsylvania Hospital was higher and they tended to be people who had Blue Cross/Blue Shield coverage and lots of other economic benefits and in some cases had preventive care and other things as part of their health care components.

In the other facility they had indigent patients, patients who were street people, patients who had less economic resources to provide themselves quality of care. They came into the facility as an acute care case, sometimes under difficult circumstances with other problems that probably should have been dealt with before.

You mentioned that economy is something that has to be looked at as well. I have noticed that a lot of the urban city hospitals have closed and that the VA has a patient load that is not only older but, apart from dealing with service-connected veterans, the nonservice connected veterans that are cared for, a large percentage of those particularly in city hospitals, are indigent veterans or veterans who find themselves in the VA because of insufficient funds or insufficient insurance and other things to provide themselves care.

Can that have an impact on the statistical base, the fact that there is a group of patients who in some instances are not only just older but who have come from a different economic background?

Dr. BAHNSON. Yes, I think so. I think that's a major factor. Neglected disease, age, these are probably two of the most important factors in the difference in mortality and morbidity.

Mr. EDGAR. Just one final comment on the press reports. I, too, have read those press reports and was surprised at a couple of them, because I have been raked over the coals in the Miami press and not one person from Miami has ever talked to me. I find that strange.

I also found the articles not to be bad articles, necessarily, and most of them were an attempt, from the information that the reporter or reporters had, to be an analysis of what troubled them. I think actually—and may differ from some of my colleagues—that they make a contribution in raising the question and forcing this committee, forcing you and the VA to ask the question about quality of care.

As I have reviewed your report and the recommendations made, and Dr. Ditzler's response, I don't think that I see any reasonable effort to either cover up the statistics or to alter the statistics to make things look good. In fact, I think we have heard, from you and others we have talked to, that, in fact, Miami, with its older population, with its economic distress, with the patient load that it's carrying and some of the unique situations, and with the change of personnel that has been made at that facility, that there is good reason to believe that the quality of care being provided there is good quality cardiac surgery care and that we have no reason to believe that the facility should be closed. I have confidence that once that information is shared generally with the

broader press that we will go on to looking at other issues and continuing to monitor this particular issue.

Would you agree with that kind of assessment at this point?

Dr. BAHNSON. Yes, I would, completely.

Mr. EDGAR. I have no further questions, except to say, do you know of any other areas of concern within the cardiac units in the Miami or the Florida area at this point that you think we ought to take a look at?

Dr. BAHNSON. No, I don't.

Mr. MICA. Mr. Chairman, a quick point of information.

Will the record be left open for additional questions?

Mr. EDGAR. That's correct. I will ask unanimous consent that questions be submitted to the witnesses and that their responses be included in the record at this time. We will give a 2-week period for that so that we can close the record.

Are there any other questions of our witness? Did we make you miss your plane?

Dr. BAHNSON. No, no. No problem. Thank you very much.

Mr. EDGAR. Have a nice lunch.

Mr. EDGAR. Our next group of witnesses will be a panel, Dr. Gerald Kaiser and Dr. Robert Myerburg. Will you please come forward at this time.

Doctors, we are really pleased to have you here and we are sorry about the delay. We thank you for your patience in listening to our two previous witnesses. The full text of your statements will be made a part of the record at this point and we ask you to proceed. You may summarize if you wish and move to questions, but it's up to you.

Dr. Kaiser.

STATEMENTS OF GERALD A. KAISER, M.D., CHIEF OF THORACIC AND CARDIOVASCULAR SURGERY, UNIVERSITY OF MIAMI HOSPITAL; AND ROBERT J. MYERBURG, M.D., PROFESSOR OF MEDICINE AND PHYSIOLOGY, AND DIRECTOR, DIVISION OF CARDIOLOGY, UNIVERSITY OF MIAMI MEDICAL CENTER

STATEMENT OF DR. GERALD A. KAISER

Dr. KAISER. Thank you, Mr. Chairman. Members of the committee, ladies and gentlemen: I wish to thank the committee for the opportunity to appear before you today. I hold several positions at the University of Miami School of Medicine, and I appear before you prepared to discuss two of these roles as they interface with the question on the cardiac surgical unit.

First, in my capacity as deputy dean for clinical affairs at the medical school, I want you to be aware that the relationship between the school of medicine and the Veterans' Administration Hospital actually goes back to the beginnings of the medical school in 1952. We are a Dean's Committee hospital and I assure you that the relationship between the Veterans' Hospital and the school of medicine is very close.

The hospital, as you heard, is located directly across the street from the medical school and the University of Miami Jackson Medical Center complex, which is the other major teaching hospital of our university. The Veterans Hospital, its staff and physicians,

therefore play an important role in the medical school in both medical student education and postgraduate residents training, as well as research.

I also serve as a professor of surgery and chief of the division of thoarcic and cardiovascular surgery and a consultant to the cardiac program at the VA hospital.

The section of cardiothoracic surgery at that hospital was established in 1972, with funding for two full-time equivalent staff positions, and the designation of the rotation to that hospital as a 6-month component in the second year of our residency program. From its inception to the present, this program has continued unchanged with the Veterans' Administration Hospital rotation comprising a quarter of our training program.

The commitment of our faculty to the VA has, from the beginning, required one or more faculty be assigned to that facility for a major portion of his clinical duties. In the past 12 years, however, there have been several changes in our faculty as can happen in an academic program and that circumstance has interferred somewhat with the team effort that is necessary in conjunction with cardiologists, anesthesiologists, and the ancillary personnel.

Also during the same period the cardiac surgical program has developed at a time when it was necessary to obtain funding from the hospital for these additional personnel, facility improvement and equipment, from a budget in which there was no specific funds for the cardiac surgery program. This has been resolved within the past year and it has allowed us to establish a program where, for example, profusionists under contract at that hospital are the same as those across the street at the Jackson Memorial Hospital Center. So we have a totally integrated program vis-a-vis the cardiac surgery aspects.

These accomplishments have been possible because we have been able to recruit an attending cardiac surgeon to the VA; namely, Dr. Lester. I believe you will hear from him later. I will only state he had trained at the University of Miami, he had extensive training elsewhere subsequently, and we believe that his previous knowledge of the University and its relationship to the VA and the importance of this program within our division, including supplemental financial support, would supply the expertise and leadership required to provide excellent clinical and operative results.

I believe he has performed in an outstanding manner and the results that have already been discussed attest to that.

I must add, however, that I believe it is difficult for both the patients and the physicians to interact and proper patient care be delivered when each is under, at times, out-of-context continuing scrutiny by the media. This set of circumstances can, as you heard, severely restrict the therapeutic options available to the patient and his physicians, as high-risk procedures may not be performed because of the publicity surrounding possible results.

We participate in a strict peer review process, a quality assurance program, and welcome both central VA administration or non-VA physician review of our performance.

I hope that with the report of this committee based on this investigation and all the material available to you, and the testimony today, you will understand that our goal is to provide the patient

population we serve in south Florida with quality care and commitment. This patient population continues to grow and also increases in the percentage of patients over age 65, which as you have heard is a potential factor in any surgical procedure, particularly in cardiac surgery. We recognize our obligations to this group of patients and wish to provide the finest care for their benefit. We believe that this care is comparable to that which is available at other hospitals in South Florida in which cardiac surgery is performed.

Once again, I wish to thank you for the opportunity to make this presentation, and I will be happy to answer any questions.

[The statement of Dr. Kaiser appears at p. 87.]

Mr. EDGAR. Thank you. We will hear from Dr. Myerburg and then move to questions.

STATEMENT OF DR. ROBERT MYERBURG

Dr. MYERBURG. Mr. Chairman, ladies and gentlemen, I appreciate the opportunity to be here today. With the chairman's permission, I would like to read only those portions of my prepared text which are not redundant to what has been read into the record already.

Mr. EDGAR. Without objection. We thank you immensely for doing that.

Dr. MYERBURG. My firsthand knowledge of the VA medical center operation derives from the fact that I was initially recruited to Miami as chief of the cardiology section at the VA hospital in 1970. I served in that capacity for 3 years. In 1973 I was appointed director of the division of cardiology for the University of Miami Medical Center which supports the VA cardiology program. When I left day-to-day operational responsibilities at the VA in 1973, four full-time faculty members continued at that facility to maintain the clinical activities.

I will now skip a portion of the written text which simply summarizes the historical problems prior to 1984 and which highlight some of the recruiting problems that we had at that time.

Now, to continue from my text, as a consequence of these successful recruiting efforts for certain key positions in the Department of Medicine, we were able to recruit Dr. Lance Lester to direct the cardiac surgical program at the VA Medical Center, and he joined our faculty on January 1, 1984. Dr. Lester has integrated well into the team concept of medical-surgical relationships and has developed the mutual respect and confidence within the cardiology group.

In addition, I would like to point out that from the perspective of the division of cardiology, other factors must be taken into consideration. As was mentioned several times this morning, the patient population with which we deal at the VA Medical Center in Miami is generally older, has more advanced heart disease, and is in a higher risk category among the overall population of surgical patients.

Dr. Lester has informed me that despite this, we have only had 4 deaths among 60 surgical procedures in the last 6 months. Three of these occurred in the course of emergency surgery, which is a higher risk situation, and only one of which was during elective

surgery. All the deaths that occurred since Dr. Lester's arrival have been analyzed by the three eminent surgeons sent by the VA Central Office in January 1985, and you have their report.

I would like to point out that from the point of view of the medical cardiologists involved in the VA program, and from my own supervisory function over that component of our program, I am satisfied that any deaths which have occurred were not outside the range of acceptable standards of surgical risk, and that, in fact, Dr. Lester is an excellent surgeon, both in terms of his technical skills and his operative and postoperative judgment.

The division of cardiology is fully supportive of this aspect of our program, of the surgical service being provided to our veterans, and of the attitude and cooperativeness of Dr. Lester and other members of the surgical department. Furthermore, I believe we are in a position to move ahead with a clinical cardiology and cardiovascular surgical program at our Veterans' Administration Medical Center which will provide the highest level of clinical service to the south Florida veteran population which we serve.

I should also point out the importance of maintaining a surgical program at our VA Medical Center in Miami. Dr. Lester will outline the magnitude of the veteran population that we serve. The cost efficiency and convenience to our veterans of maintaining this program is self-evident. Less obvious, but probably more important, is the need for a surgical program to maintain excellence in the medical cardiology program. Modern cardiology without surgical support, in a hospital the size of the Miami VAMC, serving such a large population, would be an undesirable setting for the type of bright and talented cardiologists we hope to maintain on our staff. I believe that our ability to maintain a strong VA cardiology staff is closely dependent upon the continued presence of surgical support.

I will be pleased to answer any questions you have.

[The statement of Dr. Myerburg appears at p. 92.]

Mr. EDGAR. Thank you very much, and I want to thank both of you for your testimony.

Let's assume that the report which we talked about earlier did, in fact, look carefully at the surgical procedures and suggest that from January 1984, when Dr. Lester took on his major responsibilities, that things have worked well, given the relative nature of the patient workload. Can you both speak about the period of time from 1981 up to 1984 where it seems from looking at the history there was some inconsistency and some irregularity in terms of the quality of that staffing at the VA? Is that a perception that's real or imagined, that you had difficulty since about 1982 filling that spot, and could that instability have led to some of the charges and allegations that have been made?

Dr. MYERBURG. Let me answer that from the point of view of the division of cardiology—and I am sure Dr. Kaiser will also want to respond to that from the view of the Division of Thoracic Surgery.

Let me go back a little bit further. In 1978, at a time we had a full complement of four cardiologists, three of those four individuals were recruited by other institutions because they were highly desirable, young visible people who were ready to become chiefs of cardiology in other programs. In that one year we lost our entire

staff. We hired temporary personnel who were young, well-qualified cardiologists, fully trained. There was no problem with the quality of their activity. But they were individuals who were a bit early in their careers for assuming a real directorship role. This went on for several years, and at the same time the chairmanship of the Department of Medicine at the University of Miami became open.

Now, you have a situation in which the Chief of Cardiology position at the VA, being a position in the hierarchy within the VA Medical Center complex, really requires the presence of a permanent chairman in order to successfully recruit at a high level. So we were at a distinct disadvantage in filling the Chief of Cardiology position until we filled the Chairman of the Department of Medicine position. That occurred in 1981, and by 1982 we had acquired a Chief of Cardiology for the section and had a full complement of cardiologist again.

At no time during this period of time did the ability to provide service disappear. In other words, we patched things together and made them run. The extent to which this played a role on surgical outcome is almost impossible for me to assess. If anything, it cut back the number of surgical procedures being done. I really have no data and cannot give you a meaningful answer on whether those patients to whom surgery was offered and carried out fared more poorly because of it. I have a feeling not. I have a feeling that the problem was we weren't able to offer surgery to enough patients.

Mr. EDGAR. Dr. Kaiser.

Dr. KAISER. If I go back to the same timeframe that Dr. Myerburg used, at the time that he lost his people elsewhere, we lost then a Chief of Cardiac Surgery at the VA to a private practice setting within Miami related to the inability to compete with the salary that was being offered.

With that occurrence, we had the inability to recruit, until Dr. Lester arrived, a person of the quality and the background which we felt was necessary to provide the expertise. Accordingly, therefore, it reduced the volume of surgery and had a system where we did on a case-needed basis, utilizing personnel who were not primarily based at the VA until a temporary appointment was made. So we would have a presence in the hospital to maintain on-site supervision and an individual who could participate with others in the surgical procedures.

Just a remark in reference to the quality assurance program and whether such a program could function. You may know that when we evaluated data in 1980, we were concerned and we voluntarily suspended the program to ensure that the quality was what it should be, that the results were comparable to hospitals in our area, and we did a total review not only of the personnel but of the facility needs and of the ancillary help, et cetera. To address a question that you gentlemen had raised in the past, I think that both an internal review and an external review of the peer review process is a process which can and does work.

Mr. EDGAR. Let me just ask one final question of both of you. You have been part of this setting for a long time and you have seen different physicians come through in both of your specialty

areas and the quality of those physicians has varied from physician to physician.

Have you found it difficult working with the VA to weed out physicians that you feel may not have had the highest standards? What do you do when you find a physician, either in your setting in the private sector or in the public sector, when that physician is not physically and mentally prepared to offer service?

Dr. KAISER. In answer to your first question, the hospital administration locally in Miami has been totally supportive of the surgical program, with one qualification. We could use more funds, and it is necessary to have increased personnel which is obviously a nationwide problem.

As far as their support of the quality assurance program in the evaluation of individuals, it has been total. As far as the ability to remove or relieve individuals from responsibility, that has been able to be accomplished in the VA setting and has, indeed, been performed. So I do not believe there are any rules or regulations which would preclude the proper supervision of individuals and a monitoring of their performance to ensure proper care.

Mr. EDGAR. Dr. Myerburg.

Dr. MYERBURG. The VA medical center's administration has the authority to make changes based on disability or inadequate performances. In my experience, they have exercised this authority properly and with good judgment. In fact, it is easier in the VA system to weed out problem situations than it is in the university system itself, because we have a tenure type of situation in the university that makes it a bit more difficult.

Mr. EDGAR. I yield to my colleague from Florida, Dan Mica.

Mr. MICA. Thank you.

It seems like we're talking about two distinct periods and maybe this is a part of the whole problem that we're addressing here today. But I would say there may be some discrepancy, or at least the appearance of a discrepancy, in your testimonies here just as you gave it.

Dr. Myerburg, you said that during the period of 1980–83, 1984, that you patched it together, there was no problem, and there was never a question about quality of service. Dr. Kaiser, you said we voluntarily closed it. Why did you close it if there was no problem?

Dr. MYERBURG. I believe I prefaced my statement with the fact that I was referring to the medical cardiology program. I said that I would yield to Dr. Kaiser to comment on the surgical program. The medical cardiology program was my reference point for my statement.

Dr. KAISER. In reference to the apparent conflict——

Mr. MICA. Wait a minute. Before I go a step further, I was assuming that everything we have been talking about here this morning was the surgical care unit that has been the subject of all this controversy. I don't see the other doctors here. Dr. DeBakey has left——

Mr. EDGAR. Dr. Myerburg is in charge of the medical side and Dr. Kaiser is responsible for the surgical side. There is a difference. The surgical side was shut down in 1980 voluntarily and they could continue to provide medical care but not the surgical care.

Mr. MICA. Let me just ask my colleagues and Dr. Rowland, as a member of the committee, anything we covered this morning, we were all talking about the surgical care unit? Does anybody have any different opinion on that?

Mr. EDGAR. That's correct.

Mr. MICA. OK. I just want to make this clear so there is not a discrepancy. You're saying that in that area there was no problem, and you're saying in your area there was a problem, and you decided to close down the surgical care unit?

Dr. KAISER. That's correct. In 1980 we voluntarily suspended operation so that we could evaluate the results and determine whether they were related to physician care or related to ancillary personnel needs, related to equipment, and went through an extensive review over a period of some 6 or 8 months, during which time a series of questions were addressed in all of those areas and changes were made based on that review.

Coincidentally there were changes in cardiology personnel which, as I said, since this requires a team effort, allowed us to proceed very slowly from that time forward because of the fact it is necessary in this type of complex surgery, with the important participation of the medical side and the team effort in both anesthesiology and nursing services, for example, in the intensive care units, the profusionists, the individual who runs the heart-lung machine, that all of these processes have to build and grow. It was necessary to recruit the proper individuals.

We believe that as of January 1, 1984, all of that was in place, was functioning properly, and I believe since that time the results and the performance which you have well documented has been quite satisfactory.

I think part of the confusion related to the articles that you alluded to, relates to the fact that they reviewed data from 1973 to 1983 and made, unfortunately, in my view, little distinction with what changes had occurred, and then referred only to raw data. I think it is very important for the patients, for the physicians, that data be analyzed on the basis of matching apples to apples and oranges to oranges.

I believe it is a disservice when the overall results and the bottom line is delivered, because that puts an unnecessary and undue constraint on the patient-doctor relationship. I believe it is the patient-doctor relationship and the ability of the individual patient to have his problem explained. As one of our patients said, "You told me I had a 15 percent risk. What I'm excited about is that I am one of the 85 percent that made it." They're focusing on the 15 percent who didn't. The point is, if you have a lot of those 15 percent patients, you can't have a mortality rate which is exceedingly low. That does not mean that the performance is poor. It does mean that your case mix may be different than another hospital's.

Mr. MICA. I see my time has expired. I will wait for the next round.

Mr. EDGAR. Thank you. I would just like to ask a follow-up question on that. Dr. Kaiser, isn't it general practice, both inside and outside of the VA, throughout medicine, that when a problem is determined internally in a complicated area like heart surgery, it is not uncommon to shut down a unit for a period of time to make

the corrections that are necessary and then to gear the unit up again?

Dr. KAISER. Absolutely. I think that's best.

Mr. EDGAR. Thank you.

Dr. Rowland.

Dr. ROWLAND of Georgia. I will yield to my colleague from Florida.

Mr. MICA. Thank you very much, Dr. Rowland.

Just to follow up on that point, then, I guess it would be logical to assume that you did have data presented to you that indicated there was a problem and it needed to be closed down while you reviewed it?

Dr. KAISER. In 1980?

Mr. MICA. Yes.

Dr. KAISER. Yes, sir.

Mr. MICA. I think that's important, and I appreciate your acknowledging that.

Mr. EDGAR. Would the gentleman yield?

Mr. MICA. I will, but just an additional point. You're saying there is no data that indicates that we should have a closure in the 1984 period?

Dr. KAISER. At the present time?

Mr. MICA. Yes.

Dr. KAISER. In my belief, there is no data. I think the program is functioning at the highest level that it can and it is quite satisfactory, yes, sir.

Mr. MICA. Then I would hold the question for Dr. Ditzler as to why they did close it. As you know, it was closed just recently.

Mr. EDGAR. Dr. Kaiser, could you review just briefly with us the data points that led you in 1980 to shut down the system?

Dr. KAISER. One was the overall mortality rate; two, there were some questions related to equipment; there were questions related to the personnel as they performed in these various ancillary services. We just felt that a total review of the process was needed so that we could assure ourselves that we were providing the best possible care.

For example, if you have a very large volume of service and you have a very low mortality rate of 2 or 3 percent, you might be patting yourself on the back—and with good reason. However, if you don't review that data closely, it might turn out that that 2 or 3 percent comprises 80 percent of the same type of patient, and maybe that patient is not a candidate for the procedure that you're performing, even though the overall data would tend to say things are very, very good. So we felt at the time that it was necessary to do an in-depth review and the safest way to do that was to suspend the program temporarily.

We did that. When new equipment was available and the personnel changes were made, we geared up again. There was, however, a lag in our ability to recruit the outstanding type individual that we believe Dr. Lester is.

Mr. EDGAR. Did you have to close your university setting at the same time?

Dr. KAISER. No, sir.

Mr. EDGAR. So you continued your surgical procedures across the street?

Dr. KAISER. Yes, sir.

Mr. EDGAR. Was it easier for the university to get the kind of quality equipment that you are talking about than to get it through the bureaucratic process of the VA?

Dr. KAISER. I have to say that when we did the review and analyzed what we felt could be problems, the local administration made the funds available and the facility changes; the construction and equipment are absolutely of the highest quality.

Mr. EDGAR. If you were to compare the two units on one side of the street and the other in terms of equipment, are they identical?

Dr. KAISER. At the present time, they are not only identical, but I think Dr. Lester would say he would prefer to operate in the VA setting, which has a brand new, superb operating room and all the support facilities.

Mr. EDGAR. Are the personnel the same or similar?

Dr. KAISER. The personnel are, in every way, similar, and he has been very successful in developing both the morale and team effort necessary of all the ancillary and support personnel, who are the ones who deliver the direct care to the patient once the surgeon does his job in the operating room.

It is such a complex and potentially serious type operative procedure that these other aspects become vital to the patient's success. You have to have the support facility, the laboratory facilities, within the hospital, all of which are now present. You have to have a good profusionist and anesthetist. You have to have the nursing personnel. That is in place and has been so to the degree I now describe since January 1, 1984.

Mr. EDGAR. If either of you would have a message to give to the people of Miami, Fort Lauderdale, in terms of your observation of both the university facility and the VA facility, what would that message be, in light of the controversy?

Dr. MYERBURG. I think at the present time the quality of both medical and surgical care for the patients at the VA hospital is of the highest caliber, is comparable in every way to the overall program within the university and within our community.

I think the ripple effect, as I indicated in my statement, of losing the surgical program is on the ability to perform the medical functions to our veterans, taking care of heart attacks, taking care of rhythm disturbances of the heart, taking care of heart failure, things that are nonsurgical problems, could be very serious, because the quality type medical cardiologists that you want to retain are going to want to function in an environment where there is a surgical program available. That is modern cardiology. It is a team effort between cardiology and cardiovascular surgery. The loss of either element of those would be devastating to the other.

Dr. KAISER. I would just like to say that I believe that at the present time the cardiac surgical program, in conjunction with the other programs in the hospital that support that particular modality of treatment, is of the highest caliber. I believe that the population we serve in south Florida should be confident of the fact that they can receive the highest quality of surgical care in that hospital, and that we welcomed the review of our performance for the

past year because we believe that such an in-depth review by the individuals of such impeccible credentials would reveal that this performance is at the highest level. We are very pleased to have participated in that program.

Mr. EDGAR. Dr. Kaiser, would you have any hesitency at all in advising any veteran that he or she could expect and would receive quality medical care for a heart problem at the VA medical center in Miami?

Dr. KAISER. No, sir.

Mr. EDGAR. Do either of you have any information that veteran patients are avoiding some therapeutic options as a result of the adverse publicity about the VA's medical heart surgery program?

Dr. KAISER. Yes, I do believe that the series of articles have raised questions in the minds of both patients and their families, and that this has unfortunately interferred with the patient-doctor relationship and with their confidence in our ability to provide high-quality care for their needs. It has even spilled over to affect postoperative patients who should have come back for a routine evaluation and were somewhat dismayed because of all the excitement in the newspapers.

We believe that the current program, the fact that we have reopened and that we are proceeding—you know, there is within the hospital an "underground," if you will, and they know from the very beginning whether things are good or bad. That particular information is passed to the various patient population groups. I think they have been very satisfied and understand that for the past 14 or 15 months now we have an absolutely first rate program in place and functioning.

Mr. EDGAR. I have no further questions. Dr. Rowland or Mr. Mica?

Mr. MICA. One last point. Are you convinced, sir, that these changes were being made and in progress at the point the articles started to appear, or that the public revelation of previous problems assisted, if you will, or proved beneficial in bringing about a resolution or a quicker attention to the problem?

Dr. KAISER. To my knowledge, sir, Dr. Lester was in place and functioning January 1. If I remember correctly, the first articles appeared about Thanksgiving of that year, so he had already been there for 11 months. I think the juxtaposition of the previous data and the current year was part of the problem.

Mr. MICA. Thank you.

Mr. EDGAR. I have no further questions of you. I would just make this comment, that I happen to think the closure, which we will talk to Dr. Ditzler about, and the reopening was actually healthy for the system, and that the careful review that was done was important to assure the people in the Miami-Fort Lauderdale area that they can receive care. It doesn't mean that with the end of this hearing it will be the end of our continued concern. We think that the recommendations suggested by the three-member panel not only are in place but should be continued in place and that some of those recommendations need to be instituted at other VA facilities so that the best quality of medical and surgical care can be provided in this area of heart surgery.

I think that valuable points are made when we force ourselves and the general public and the press to look beyond just the statistical numbers, to both the issue of age, the issue of condition of the patient, the issue of economics, the issues that were raised earlier today. We appreciate your taking the time and the energy to be part of this process.

I yield to my colleague from Florida.

Mr. MICA. Just a quick question before you leave, Dr. Kaiser, and we, too, thank you for being here. I recognize this is a subject of immense complexity and that is why we have tried to be very, very careful in analyzing the data and the information we have had.

Does the University of Miami have any criteria such as excessive mortality rates or any other criteria on patient selection that is more limiting than the VA? Do you have a rate where if you say we have this problem we don't close down and the VA continues, or we accept patients they don't?

Dr. KAISER. No, sir.

Mr. MICA. None at all?

Dr. KAISER. In fact, as you may know, Jackson Memorial functions both as a hospital tertiary care center for private patients and is the county hospital for Dade County, so a lot of the patient population we serve is medically indigent and are similar to the VA population. In fact, we have very similar criteria for evaluation and there is no difference, no, sir.

Mr. MICA. Do you then have the same mortality rate?

Dr. KAISER. Roughly similar, yes, sir.

Mr. MICA. Thank you.

Mr. EDGAR. Can either of you send me information on cholesterol buildup in the blood? [Laughter.]

Dr. KAISER. That's a medical problem.

Mr. MICA. And triglycerides.

Mr. EDGAR. I'm a jogger and I keep watching Jim Fixx——

Dr. KAISER. I have to tell you what Dr. Shumway said when asked whether he jogged. He said, "No, I would rather be sick when I die." [Laughter.]

I would also tell you that my definition of a premature heart attack is a heart attack in a patient 1 year younger than the doctor examining him. [Laughter.]

Mr. EDGAR. Thank you very much for your testimony today.

Our final panel will be led by Dr. John Ditzler, the Chief Medical Director, and he will be accompanied by Dr. Robert Laning and Dr. Joseph L. Lester III.

Dr. Ditzler, before you introduce the extra person who is with you, I would just say that the full text of your statement will be made a part of the record, and we appreciate your patience this morning.

Please introduce those who are with you today and proceed.

STATEMENT OF JOHN W. DITZLER, M.D., CHIEF MEDICAL DIRECTOR, DEPARTMENT OF MEDICINE AND SURGERY, VETERANS ADMINISTRATION, ACCOMPANIED BY ROBERT C. LANING, M.D., DIRECTOR OF SURGICAL SERVICES, DEPARTMENT OF MEDICINE AND SURGERY; NEAL LAWSON, OFFICE OF GENERAL COUNSEL; AND J. LANCELOT LESTER III, M.D., DIRECTOR OF CARDIOTHORACIC SERVICE, VA MEDICAL CENTER, MIAMI, FL

Dr. DITZLER. To my left is Dr. Robert Laning, who is the Director of our Surgical Service, and to my right is Dr. Joseph Lester, the Chief of Cardiothoracic Surgery at the Miami VA Hospital. To my extreme right is our legal counsel from the VA, Mr. Neal Lawson. He's here to keep me out of trouble.

Mr. EDGAR. I'll try to keep you out of trouble, too.

Dr. DITZLER. Thank you.

I most appreciate being asked here today, and I do not plan to read you my entire statement. Let me extract, in part, some of the remarks I have in the printed statement.

First of all, I believe that cardiac surgery is a most closely monitored VA surgical program. Only one other comparable group of cardiac surgery programs, to my knowledge at least, is in New York State, which is that closely monitored.

For this and other reasons, the overall mortality rate of open heart surgery has been reduced from 16 percent in 1969 to now an average of about 4.7 in 1984. But in this same timeframe the total number of cases which include valve replacements and coronary artery bypass has increased from 637 to 6,450.

The VA mortality rate exceeded the rate for the civilian community in the early 1970's. However, today it is roughly equivalent. Credit for this reduction of mortality is given to improved technology, accumulation of experience, and close surveillance of the program.

Some of the private sector reports define mortality as only that which occurs in the operating room at the time of surgery. The VA mortality statistics include those cases that not only died in the operating room, but also add all those cases that died, for any reason, within 30 days after surgery, and as a result of any complication that first manifested itself in those first 30 days and continues on.

Private sector reports tabulate mortality for coronary artery bypass alone. The VA statistics include both bypass and valve procedures. The mortality rate for valve replacement, for example, is nearly always higher than that for coronary artery bypass.

With respect to the Miami program which we have heard about considerably, I think it important to mention that on December 10, 1984, the consultants to whom we have referred, who are non-VA physicians, had a concern also and had planned a visit to the Miami VA. Also at the same time a series of articles were published in Florida newspapers. Allegations of excessive mortality in the cardiac surgery division at the Miami VA Medical Center was then reported. Such publicity results in understandable anxiety among candidates for surgery and could increase the risk. Therefore, we temporarily suspended the program pending review by the team of eminent cardiac surgeons, some of whom you have heard

today. I think the review, in retrospect, has gone far to help allay the concerns of the veteran patient.

One of the recommendations that I made and am proud to announce is that Dr. Lester, the cardiac surgeon, certainly should be encouraged to continue his work at the VA Medical Center and I think he deserves very high praise for his accomplishments.

I think it important also to say that, in addition to our agency-wide examination of cardiac surgery at all VA facilities, which has been initiated, that we have also formed a 12-member panel of expert physicians from outside of the agency with expertise in cardiology, cardiothoracic surgery, anesthesiology, and medical ethics. They held their first meeting this week, Monday the 18th, here in Washington. Their mandate is to review and revise on the appropriate numbers locations of VA programs and what should be considered acceptable mortality rates and the ethics involved considering the high-risk factors for surgery and anesthesia in our population. I have requested that this group provide a report upon the completion of their deliberations, which I will be happy to furnish to you.

Mr. Chairman, I simply want to assure you, and the members of your committee, and the public, that the veteran patients and the quality of the care we render is our top priority.

I stand ready for questions.

[The statement of Dr. Ditzler appears at p. 95.]

Mr. EDGAR. Thank you.

Before questioning, do you have any comments you would like to make, Dr. Lester, about your service at the Miami Medical Center based on the comments made today, as well as the review that has taken place?

STATEMENT OF DR. J. LANCELOT LESTER III

Dr. LESTER. Yes, I do.

Mr. Chairman, Congressman Mica, members of the committee, I have about an hour long statement that I would like to read to you all prior to lunch. [Laughter.]

There are some critical remarks that I do think need to be made, and I feel this is an opportunity which is difficult for me to forego. I find it also difficult to read my prepared statement, but I would like to summarize, as best I can, those circumstances that we have faced and in some respects will continue to face for some time.

Mr. EDGAR. Without objection, your full text of your statement will be made a part of the record.

Dr. LESTER. The results of the VA over the prior decade were criticized in the local media, and basically there were five allegations that were made. You have already heard some of those, but to summarize them:

One, the results were poor and they could have been better. VA representatives and VA officials and surgeons and members of the Miami VA system did make very significant changes in personnel and equipment. As Dr. Kaiser mentioned, the equipment at the VA is clearly better than the equipment at the university, judging by the standards of those places where I have worked, including

Emory University in Georgia, the Cleveland Clinic in Ohio, and the Ford Hospital in Detroit, MI.

The responsible individuals did perform those corrective measures.

The volume was low, that is, it was less than 100 cases a year. At the time our program was closed over an 11-month period, we performed 95 cases. We would have gone over 100 in that year. If you look at our last 3 months, we were operating at a rate of approximately 150 cases a year. That would have positioned us, if you will, in the next year or two to perhaps 200 cases a year. That would have been a high volume center of excellence in very short order.

So the answer to the question of should programs have been consolidated, I think one Miami VA, for a region that serves 600,000 veterans, was positioned to be a geographical center and was, in fact, a center both in terms of volume and in terms of, I believe, improving results, if not of excellence, at the time.

One other allegation was made, that the results are much better in private centers. There are about 500 cardiac centers in the country and about 2,000 cardiothoracic surgeons. It is a very small group of people. Those in south Florida are known to me intimately in terms of both sharing training experiences and social functions. They report their results for coronary artery disease as 1, 2, 3 and 4 percent. We have reports from their hospitals, from either the chief surgeon or the chief cardiologist at the four other hospitals, including the university, that do the next highest volume of surgery. All of those centers reported results in excess of 5½ percent. The highest mortality was equal to our average for the year 1984 and we were right in the middle in terms of the last 6 months, or at the low end of the scale.

So all of those allegations about the prior decade were either answered by actions accomplished during that decade, or during the year of my tenure.

The last group of circumstances I would like to summarize is that when we went to the Miami VA we recognized that it had had some problems. We recognized that it existed in an environment of a huge number of veterans in need of surgical care, that we would probably go over 200 patients per year within a short period of time, that we would have a high mortality if we tried to serve the sickest patients. We had two options. We could either decline the sickest patient, or we could accept that risk. So, after an initial cautious period, we began to operate upon high-risk patients at the urging of both the patients and their medical doctors who made those recommendations. That resulted in an overall mortality rate of 9 percent for the year and a mortality of 6.6 percent for the last 6 months that resulted in elective mortality of less than 2 percent, which is equivalent to Dr. DeBakey's program or Dr. Cooley's program. Elective mortality in patients not admitted to an intensive care unit during that hospitalization was equivalent to national centers.

I think it is important that you recognize that the centers with the lowest mortality may not be serving their patient populations. If you work in a VA hospital and do not operate upon sick patients, and accept the probability that you will have a higher operative mortality than a center that operates on predominantly elective

patients, it is like being a doctor in a jungle and not serving patients who have malaria. We have to treat patients that are at a higher risk.

For instance, in the major medical centers many focus upon stable coronary artery disease, patients who do not have acute symptoms. Those patients can travel freely. They may arrive at the hospital with their bag in hand, walking briskly and saying "I'm here for my cardiac surgery." Few of our patients arrive in such a condition. In addition, if you look at our figures and eliminate those patients who can travel, we have the high risk population. Or, said another way, if only those patients who could travel were operated upon in our hospital, seven of the nine deaths would be eliminated.

So, if we function as a tertiary referral center, geographically removed from our patient population by enormous distances, hundreds or thousands of miles, we would have an extremely low mortality.

I give you this information not to violate the rules about the process, but because all that information is known to me. I go to bed at night thinking about the patients that need to be operated upon, upon the risk, and whether it is prudent for the program to be operated. So, I see a setting in which if the lowest mortality is utilized, I, as a physician, will not serve the purpose that I believe my training permits me to do, which is to operate upon sick people. If I pursue the lowest mortality, I can generate that number for you at 1 percent forever, but I will not be taking care of the patient population which I am obliged to serve.

[The statement of Dr. Lester appears at p. 102.]

Mr. EDGAR. Thank you, Dr. Lester, for your statement.

Are there any pieces of equipment that you feel are necessary to improve the quality of your care within the VA hospital that you don't presently have?

Dr. LESTER. I know it is difficult to believe—and I had the same problem with some of my friends and colleagues—the equipment that exists within the VA hospital is among the finest that can be purchased. I will give you some examples.

At the time of the closure of the program we had five intensive care beds devoted to cardiac patients. That's about the equal number for hospitals that are substantially busier. For the three patients that were considered not to be so ill we had, if you would, one private cubicle for one of them, and a closed in area for two of them, so they would not be disturbed by the noise within the intensive care unit, and one nurse assigned to them.

We have a computer analysis monitoring system which permits us to retrieve data over hours or within the last few days, both in terms of the patient's blood pressure, heart rate, arrhythmias, and the laboratory data so we don't have to call on the phone for laboratory data. It is equivalent to and superior to the equipment available at the university.

Now, I spend a substantial amount of my energy at the university when I operate there complaining about why can't I have the same excellent equipment that I have at the VA hospital, which I am sure is a novel experience.

It is not a question of equipment. It is a question of degree. If you pursue the degree, the equipment is clearly superior at the VA hospital at this moment in time.

Mr. EDGAR. Let me ask about staffing for all of the auxiliary services that you need to provide quality of care. Are your staffing levels in each of those categories to your satisfaction?

Dr. LESTER. It is. I must tell you that those individuals and those resources were provided, with some administrative difficulty, to the cardiac program; that is, it was considered a priority program. When I arrived they had made major commitments. My past administrative responsibilities within the university had suggested to me that we discuss those things ahead of time, and we did. Those commitments were honored totally. So I had no reservations about either equipment or personnel.

I am sure there were some people within the VA system who might have complained the personnel were provided to the cardiac program and they might have wanted their share of that pie.

Mr. EDGAR. Do you have any difficulty with any of the recommendations that have been made by the three-member review team?

Dr. LESTER. The majority of the recommendations, or all of the recommendations, essentially attempt to formalize what we had already been performing, in my judgment. They do not result in a substantial change in the conduct of care.

I must tell you that there is a clear sense that high risk patients cannot be operated upon in our institution unless we achieve mortalities comparable to elective patients in the immediate future, so that we are under some pressure to perform elective surgery primarily on our patients. That is one substantive, if you will, nonrecommendation that has emerged as some natural consequence of this discussion. That is, if I continue to operate on patients with a 6 percent mortality overall, the fact that I have a low risk group of patients that have excellent national results comparable with similar patients will not justify the support perhaps of Members of Congress or members of the press. So we are under some pressure which is not a formal recommendation of that committee but has emerged, if you would, as a sense of caution among the members of the team.

Mr. EDGAR. It is my hope that as you gain experience and respect from the changes that you have instituted, and the rates that you are able to maintain, that that burden can, in fact, be lifted and you can make medical judgments as to what the patient's best needs are as opposed to feeling that outside pressure.

Dr. ROWLAND of Georgia. Would the chairman yield?

Mr. EDGAR. I yield to the gentleman from Georgia.

Dr. ROWLAND of Georgia. There is a difference in operating on people with stable versus unstable angina. Am I understanding you to say now that at this point you are not going to be dealing with people that have unstable angina there as much as you will those who have stable angina?

Dr. LESTER. Well, I think that approximates the change; that is, after a short period of time, we felt—there is a difference in what physicians will operate upon. I have had intimate contact with perhaps about ten cardiac surgeons over the last decade. I tell patients

not only what I believe and recommend but what the average national consensus would be, or what number, of all the physicians I work with, would operate upon you, or if none of them would. If you are a desperate person and you want us to do desperate things, we can or cannot accommodate you in an attempt to prolong your life or make it palatable.

In this case we are certainly under some pressure to generate specifically low mortality figures. I believe that does not serve the patient's interest. I do not believe that a continued public discussion of each piece of data, of each death, of each consequence, of each problem, serves those patients, because what will happen is what has happened in other institutions: clearly, people will deny surgery to the high risk patient because the institution cannot tolerate it. It's not a question of whether the patient needs it, but the institution cannot tolerate high mortalities.

So it is important that patients have the option, if they are desperate, to get the care they need. That is served by an informed judgment about what the risk is. So to some extent, yes, I would rather not be operating upon unstable patients. In the past I have transferred patients that I now might operate on, and currently have transferred patients to other institutions, that I might operate upon at the Miami VA.

Dr. ROWLAND of Georgia. So we're talking about good statistics versus good patient care?

Dr. LESTER. I think we are. I think that is a national issue which has not been addressed. It is because, as I say, the national centers receive a totally different category of patients than do individual programs receive their patients within a small geographical zone.

Dr. ROWLAND of Georgia. I will have some questions but I will yield back.

Mr. EDGAR. Thank you. I appreciate that.

I apologize to my colleagues for taking these questions, but I do have a lunch that I must go to and I'm going to ask Congressman Mica to take the chair and complete the round of questioning.

But let me just conclude in two areas. Again, Dr. Lester, can you describe briefly the supervising and reviewing process that you are now under?

Dr. LESTER. First of all, you should understand that every cardiac surgical patient has also been a medical patient; that is, with very rare exceptions—and certainly in the medical center there it is the case—every patient has a recommendation that he should have surgery from a medical physician at the time that surgery is considered and/or performed. So, we have always——

Mr. EDGAR. This is a second opinion?

Dr. LESTER. Yes; that is, the patient has always gotten two opinions. He has gotten the option of one or two cardiologists, he has had the acquiescence of his medical physician if he's not a cardiologist, and he has had the acquiescence of the surgeon. So, you could say that, in general, a second opinion involves the second surgeon. But every patient has had the opinion of two physicians, one of them a medical physician who presumably would not recommend surgery since he does not stand to benefit from that impact in the private sector, or in our case would not benefit since he does not

perform the surgery. He has no profound emotional involvement in it.

Mr. EDGAR. Are there any other supervisory procedures?

Dr. LESTER. Yes; these patients have been presented in the past, the nonroutine patients, to the surgeons that base their practice primarily across the street at the university, and particularly difficult ones have been reviewed in more or less detail. The effect of the recommendations was to make that a more formal process and to that end we have documentation in each case.

Mr. EDGAR. Thank you very much.

Dr. Ditzler, in your view, has the VA, both at Miami and in Washington, complied with both the letter and the spirit of the law with respect to the release of information to the press from your inquiries and your quality assurance reviews at Miami?

Dr. DITZLER. To my knowledge, we have complied as completely as we can under the current provisions of the law.

Mr. EDGAR. Could you and should you have acted differently, looking at the matter now in hindsight?

Dr. DITZLER. No, sir; I believe that the public airing and public concerns and the press that existed at that time in Miami probably would only be resolved with such an airing as we are having now and have undergone through a thorough review by outside experts.

Mr. EDGAR. I am going to submit some questions for the record, but because of the pressure of time, let me just ask this one final question in this area.

We had the three-member review panel make their report to us today, and we had a little bit of discussion as to how much or how that report can, in fact, be released. Do you recommend any changes in the present law or process whereby problem situations in hospitals similar to Miami might be handled differently?

Dr. DITZLER. Not really, sir. I believe that, above all else, one has to protect the peer review process or you will have nothing but sterile mortality figures. We have to be allowed to discuss, on an individual basis, whether a given rate of mortality is or is not excessive.

Whether Miami's was excessive or not was the issue that was before the press and the public. The issue was not whether they were at any certain rate. The figure really is irrelevant. The question was what were the figures and the problems involved in it. Once it is determined that for what they were doing the rate was not excessive, then one has, I think, an adequate review.

The ability to conduct that finite judgment as to the state of real peer review really cannot be done in a public window. The results of it, however, can be made public, but not the process itself.

Mr. EDGAR. Let me talk about that for a second. It seems to me that the integrity of the process is important, to have the ability to go out and get private physicians and have them review a particular area, and they will give you a technical document with their recommendations—is that correct?

Dr. DITZLER. That's correct.

Mr. EDGAR. Why can't you then take that technical document with its recommendations and use that in your input to give a report to the public on the findings of that three-member panel, still keeping and protecting the integrity of their report, but, in

fact, taking those recommendations and—I mean, there were questions earlier as to whether or not the physician could read the recommendations in that report. It seems to me it is ridiculous to have those recommendations laid out, that aren't necessarily sensitive—they are recommendations which not only did they make, but you accepted—wouldn't it make some sense to have a procedure where a public report could, in fact, be made from that private data that you and the VA have received?

Dr. DITZLER. I submit, sir, that the report that I rendered immediately after receiving their report was, in fact, a complete report of their findings.

Mr. MICA. Mr. Chairman, would you yield on that point?

Mr. EDGAR. I yield to the gentleman.

Mr. MICA. Dr. Ditzler, I guess this is where there might be some political-medical distinction in the way we read the results. This is one that I am starting to think, as I listen to all the testimony here, that maybe the VA's use of its own secrecy rule created part of the situation that didn't allow for the type of answer that had the credibility of the headlines, whether they were correct or not.

For example, you had a headline that did say, "Miami VA mortality rate in the cardiac unit twice the national average", with the VA saying, "it's not true, we can prove it, but we're not going to show you the statistics. We have ruled that it is not correct." It leaves a perception out there that there is something to hide.

Now, in the normal medical field, a doctor who is outside the realm of government and public scrutiny, doesn't really have to deal too much with that. Since this is public funding, since this is a public process we go through, the minute that confidence is undermined, the only thing I would see is a continued "yes, it is" from the press and "no, it isn't" from the VA and nobody wanting to share.

I would agree with the chairman. Maybe we could just recommend at this point—and I don't know how we could resolve it—that we look at a better way or have a delineated process to get more information to reporters and the press without undermining the integrity of peer review.

Now, I understand if you can't get doctors who are specialists to comment, we're out in the cold, because we're lay people. If they are not going to comment freely and effectively, then there is no use in even having the review. But in looking back at what I have seen, the evolution of this whole situation, it appears that the VA's own secrecy rule has probably allowed it to compound. Maybe that's a misinterpretation, but that's what it looks like.

Mr. EDGAR. Before I yield to Mr. Mica to take the Chair and Dr. Rowland for some questions, let me say two things. I have reviewed this situation very carefully, have reviewed the reports, reviewed the allegations that have been made, and I have appreciated the testimony here today.

Dr. Lester, I think, from my perspective as chairman of this committee, that you not only have been given a responsibility that is difficult at the VA hospital, but you have performed your responsibility very well. And while you will be under some continued pressure over the next year, I think you should go back to Miami feeling pretty good about the fact that three independent physicians

reviewing the data, looking at the facility that you operate, have, in fact, come back and said that with these recommendations in place they believe the situation is a quality care facility and that the cardiac unit should continue. I want to say, as a Member of Congress, who has reviewed this and other situations like it, that I think you should feel pretty confident that since January of last year, and hopefully on into the future, you're running a pretty good operation there.

Dr. Ditzler, let me just say to you that I think it is important to make as public as possible the data and the results and to help the public understand the complexities of mortality rates. I think we did that to some degree in the hearing today. I think we need to continue that in each of the areas of care. I think that my mission, as chairman of this committee, is to improve and keep the quality of care at all of the veterans' hospitals as high as possible and to recognize that in each of the different services there is a differnt set of problems. I think, as you come on as the new Medical Director, one of the things that you must do with us is to try to interpret how we can make the specific improvements in the quality of that care possible.

Now, we cannot always give a clean bill of health to a medical facility. There are problems within the system. I'm going to be as vigilant as I can at looking at those problems wherever they are. But I want to say to you and for the record that I am satisfied in this case and hopefully over the next several months we can get back to providing that quality of care in this facility and we will continue to watch and monitor those results. That's just my view as chairman of this subcommittee and I wanted to state it publicly.

Let me yield now to my colleague, Dan Mica, to be Chair.

Mr. MICA [presiding]. Mr. Chairman, before you leave, I would like to thank you for convening this hearing and tell you how much I appreciate it. As I said earlier, we have tried for several months, since this information became public, to always indicate that it was our desire to set the record straight or correct any problems that exist. I think this hearing has been extremely helpful and without your cooperation it couldn't have been possible.

I hate to do this right now, but I want to keep my record perfect. I have never missed a hearing in 6 years without saying that 5,000 veterans a month move to the State of Florida, and we need all the funding we can get. [Laughter.] That's something we have done every year, and in every meeting I have been to. I think maybe that's a humorous comment that I have tried to drive home, but I want my people from Florida to know that we have tried and I think we have gained a sensitivity from every member of this committee that we have severe problems in Florida with our tremendous growth. We have gone to bat for a million here and a million there, a new hospital and a study for hospitals and clinics, and so on, and my background and my feeling about the State of Florida is that we were for some years left out in the cold and now there is a sensitivity here.

With that, I would like to get into some questions, and also tell you, Dr. Ditzler, that I would like to compliment you on the way you have handled this. But I do think that some of the problems I mentioned earlier, with the way the VA rules are interpreted and

dealt with and then translated into public statements, has really created some of this question.

With that, let me ask you, why was the facility closed in this most recent episode?

Dr. DITZLER. Mr. Chairman, I think the easiest thing in the world would have been for me to ignore the whole thing and to send a group of people down there to look at the situation and report privately as, in effect, they eventually did.

The problem was not that simple. It was a problem of public hysteria, public confusion, outcries from various sectors, that was not going to be solved by an internal review, even though I know it might have been excellent. The situation had to be resolved by quelling the concerns of the public.

Mr. MICA. Did you close it, or was it voluntarily closed?

Dr. DITZLER. Well, it's sort of a toss up. I recommended and they sort of turned around and did it of their own accord.

Mr. MICA. I must tell you my staff was concerned because it seemed to me, in the period of 2 or 3 days between my staff and the press, we were picking up reports in the paper of one mortality rate being reported and then the next day another mortality rate. I think we had a total of three in less than a week.

Dr. DITZLER. That's correct.

Mr. MICA. Was there administrative problems there?

Dr. DITZLER. Well, the report that Miami mailed in to us is the one that you were first acquainted with. They subsequently changed that report about a week later on a revalidation of statistics. Part of this is a statistical fluke, like many statistics, in that our years are reported from fiscal years, October 1 through the next October 1. The results, essentially, therefore, were reflecting activities not chargeable to Dr. Lester. So, the reports we are now talking about, the excellence of the program now in place, in large measure reflects the work of Dr. Lester who really didn't begin until January 1984. So, we had a statistical fluke that was the first problem.

The second problem was, as testified to here earlier by others, much of the data being quoted from the press were for years even before that.

Mr. MICA. The specific headline, "Miami death rate twice the national average," that specifically was of a period prior to Dr. Lester, and that specifically was an inappropriate headline with regard to the case-by-case analysis of the——

Dr. DITZLER. No, sir, but it reflects very clearly what's wrong with speaking about death rates. It is correct that at the time—and I believe Dr. Lester mentioned it a moment ago—that their mortality rate for that period of time was 9 percent. It is twice the national death rate. But death rate alone is not the issue.

If one is operating on the types of patients Dr. Lester describes, it may be wholly appropriate that his death rate be that. So, we lead ourselves into a trap when we speak of death rates. The statements of the press that it was twice the national average were correct, also. But the public doesn't know what that entails. So, I think, we in truth do ourselves a disservice when we often talk about death rates because they are almost meaningless.

Mr. MICA. I have to tell you, as of this hearing today, from the information we have been given, I would agree. I would think we need to continue to make sure that any time you talk about death rates you talk about the accompanying individual statistics and problems.

Dr. DITZLER. I, certainly, intend to.

Mr. MICA. Let me ask you, it was stated and there was some concern that maybe the Miami VA hospital was, indeed, operating on people that others wouldn't have operated on, and that maybe there was too liberal a judgment in that area.

Has that question been addressed?

Dr. DITZLER. It has been addressed but I don't think it will be resolved for a long time, because as Dr. Lester says, this is an issue that is national, not only VA but non-VA. It is a touchy issue and it is to that end that this select committee that met for the first time this week on my behalf was formed. The committee includes specialists in cardiology, anesthesia, surgery, medicine in general, senior distinguished physicians, including physicians renowned in the field of ethics. We are trying to help surgeons and other medical specialists deal with these problems.

I suspect that the problem will grow worse as the future aging of America occurs, so we need to be prepared for it. But I do not think we have a final answer.

Mr. MICA. What I'm getting at is, would anybody look at those who died in the period in question and say no surgeon should have really tried this operation, that this fellow was beyond the stages of—is that type of a judgment made, or it was never a question?

Dr. DITZLER. I believe that question was addressed to Dr. Bahnson, and I believe he said that, although he found no problem with the case reviews that he or his group had done, he also said that maybe during a certain time, had he been there, he might have made a different judgment. But that's an individual judgment matter.

Mr. MICA. Along those lines, are there basic operability standards, that if an individual doesn't meet some basic criteria, he is or is not operated on, minimums or maximums? Is there a range, or is it all individual judgment?

Dr. DITZLER. I will defer to my surgical colleague.

Mr. MICA. Dr. Lester.

Dr. LESTER. I think I can tell you that I know the specific case that Dr. Bahnson probably had in mind, having spent a substantial amount of time with those three panelists. Let me describe to you the patient and perhaps you can render the judgment of what you would do if you were him or his family.

This was an individual who had spent 3 weeks in an intensive care unit, with essentially continous or intermittent pain; had previously been operated upon and had very difficult coronary artery disease. I believe that 7 out of the 10 surgeons with whom I have worked in the past in major centers might not have operated upon this individual. Not only did we discuss with this individual the terms of the raw mortality rate for our center and for his subset, which we thought was high—and we couldn't tell him how high specifically, but it was probably 15 or 20 percent. We told him basically that we, as individual physicians, did not want to operate

upon him because it was an unpleasant task for us to have a patient so sick, with such a high probability of having to tell his family and loved ones that he, in fact, was dead that afternoon. So, we went through a very graphic discussion with that patient, as we do with most patients.

His position was very simple:

> I am being tortured by the circumstances of my disease. I cannot live this way. If I die during or after the operation, I will at least be free of pain. I would like every attempt made to make my life livable.

Let me juxtapose that with another patient that came to us, who allegedly visited both of the major Houston hospitals, one other hospital in the East, and two other VA's, three regional hospitals who declined. The patient had pain when he brushed his teeth, when he walked, and sometimes when he watched TV if he took five or six deep breaths. He said:

> I spent 2 years, while insured, trying to get someone to operate upon me. I have now run out of funds. I came to the VA because I was a veteran and you're my last resort.

I must tell you that at the time he did not tell me he had been turned down by all of those institutions. He declined to mention the VA's and the local regional hospitals, but just said, "Look, I'm desperate. You've got to do something for me. I'm not going ot leave unless you do something for me."

That individual did fine. He is active, vigorous, and feels like he's 20 years younger. He does not have pain 5, 10, 15, or 20 times a day. He is alive and well. The other individual is unfortunately not with us. But which one of you would trade places with those people and not want something done? For those of you who are active and who cannot bear essentially to be in a metabolic prison, locked in your chair and unable to share the slightest enthusiasm for any events about you, or even have pain when you're doing nothing but breathing; I would submit that for them that was the best and only option.

I, certainly, did not enjoy having to participate in that and discuss that with those individuals. This is not what surgeons want to be doing and not what institutions want to be doing. But for those people, that is service against the need for the institution to have a pretty number on the page.

Mr. MICA. I will call on Dr. Rowland, but let me just respond. You said you make the judgment. I would tell you, from what you have described to me, that what you did would be, in my estimation, something you should be commended for, not condemned. The result was, though, a public question. I would commend you and I do for those specific instances, the way they have been described. I don't know any of the other details.

I guess if there is a task before us, it is to make sure that when you do something that is commendable, that the praise is there and not interpreted, which could be, as in this particular case, just a horrible 360 degree reversal of what we should be seeing happen. In those cases, you asked me to make the decision, I would say it is very commendable to take a risk when no one else would, to have a facility that our Government operates that would even consider doing that. I think that is very commendable.

We still probably are going to have to come back and deal with what you pointed out, that maybe now a negative pressure, because of the misunderstanding of mortality rates, and taking those risks. I would submit to you that determinedly as I have tried to get to the bottom of this, I would do everything I can to create a situation where you don't avoid those risks, where you try to take a chance to help somebody.

Dr. Rowland.

Dr. ROWLAND of Georgia. You opened up a question that has always been a quandary to deal with, those doctors and physicians that treat medical versus surgical patients.

If a person came in with a medical problem, for example, severe keto-acidosis, and you're on the verge of death, there would be absolutely no physician that wouldn't do everything that they could to help save that patient, regardless of what the statistics would show.

Surgeons find themselves in an entirely different situation and it is just a problem you have to deal with within the profession, deciding to know what to do, knowing that you're much more likely to be criticized as a surgeon for attempting what might be an almost impossible feat, but yet compelled to do what you can to at least give the patient a chance at some sort of quality of life they wouldn't have otherwise.

Thank you.

Mr. MICA. Thank you.

Dr. Ditzler, let's come back to this a minute. Are you making any recommendations outside of the medical area to deal with this in a way that if, indeed, there is a reported problem or a perceived problem, that it can be dealt with in a way that we don't have a pressure now, as was described, not to operate?

Dr. DITZLER. Hopefully, my select committee is going to set up standards. Now, that is something that also in the same breath is an anathema to physicians, because physicians don't normally like to practice by "cookbook." But, on the other hand, if the hue and cry of whatever attention-grabbing source brings to the individual patient the threat of the fact that he may be treated in a substandard facility, then we're going to end up with some kinds of standards that we don't really want to face, such as we won't operate on a guy such as Dr. Lester described if he's 80 years of age or older. Well, that could be proven wrong tomorrow by some distinguished person 82 being successfully operated on. So, standards are really an anathema but, on the other hand, in order to protect the decisions required in medicine, sometimes that may eventually come out. Hopefully, not for a while. Hopefully, we can continue to tell the world that mortality rates are just one little pittance of the answer and we have to look at it in detail.

Mr. MICA. Dr. Lester, you had a comment?

Dr. LESTER. I just want to say that the whole discussion of coronary artery disease is clouded, specifically coronary artery disease, because the entire body of knowledge deals with patients of relatively low-grade symptoms who could be randomized into two groups. It is a totally different context. The patients who seek attention under more desperate circumstances, really the more usual circumstances, are much more desperate—the so-called CASS

study, which was specifically aimed at finding patients who weren't very sick, or the original VA cooperative study, or the European study—totally different groups of patients from the basic data base that we work with when we try to look at a study, versus the groups of patients by and large being treated in this country at local regional centers as opposed to national centers.

Mr. MICA. Let me just ask the staff if there are any technical questions that we have left. All right. Let me give my summation, if I may, and thank you for being here.

I think that first there was a problem that was acknowledged, that did exist, apparently, over a certain period of time. Steps have been taken to correct that problem. It has been pointed out here that much of the information that was of concern may have dealt with a period before the steps were taken. That right now both Dr. DeBakey and the team are totally convinced of the viability and the quality and integrity of the Miami VA cardiac unit.

I would also say my own observation is that possibly the use of VA secrecy laws and the way it was handled may have allowed this to become more of a concern than had we had a better mechanism to deal with it. I hope we can find a way, and possibly this national team, as it reviews all of the facilities, will make some recommendations to that end. I think maybe that's a positive result of the press disclosure of this entire situation. The negative, as I see it, would be that those in Miami might, because of local pressures, or human pressures, as you termed it, be denied that extra opportunity for assistance because of concerns over mortality rates.

Also I would add, as you indicated, it has become very clear here today that mortality rates should never be used as a sole determinant of the quality of a program; you have to look at the types of individuals and the operability and the rates on a comparative basis.

I am heartened by Dr. DeBakey's report. I am relieved in the sense that the mortality rates appear to be, last year, in line with what is acceptable. I think a number of the questions that came to mind during these 6 months probably could have been answered if we would have had and maybe the press had had a more clear channel to get this information.

I don't think there would have been any way, short of this congressional hearing, to start to clear the air, and it shouldn't end here. We are going to have to continue to focus on this because my assessment is far more people have heard of the problems than the fact that the present situation is being corrected, or even will hear of this one individual hearing.

I am concerned about the low rate of procedures and I would indicate that we probably want to follow that to see that it's at a level that all in the profession would consider at least a minimum necessary for a quality program.

So, at the moment I think there should be confidence in the Miami VA facility. I would commend each of you for your assistance in helping us make this determination. I am hopeful that we can find some better ways to get the statistics out that prove that what you're saying is not in any way some attempt to wash aside valid criticisms.

Dr. DITZLER. Mr. Chairman, may I suggest that we all start thinking and talking with our press friends about rates of mortality or morbidity as being triggers to ask more questions and not letting it be an end result to judge the quality of core being provided. I think that might be a good start.

Mr. MICA. I agree with that.

The only other point I would like to reiterate for the record, we have tried to cover a mountain of information. We have a folder several inches thick of the allegations and counterallegations and so on. The chairman did indicate that the record would be left open for previous witnesses, and I would like to leave it open for the present witnesses for about 2 weeks, so that we can try to answer any questions that come up as a result of this hearing, or any that we didn't have an opportunity to ask.

We thank you very much.

Dr. DITZLER. Thank you, Mr. Chairman.

Mr. MICA. The hearing is adjourned.

[Whereupon, at 12:30 p.m., the subcommittee was adjourned.]

APPENDIX

MICHAEL E. DeBAKEY, M. D.

Biographic Sketch

Michael E. DeBakey is Chancellor of Baylor College of Medicine and Chairman of its Department of Surgery. He is also Director of the National Heart and Blood Vessel Research and Demonstration Center, Houston, Texas.

During his surgical career, Dr. DeBakey has made numerous contributions as a medical inventor and innovator, a dedicated teacher, and a medical statesman. While still a medical student, he devised a pump which, years later, became an essential component of the heart-lung machine that made open-heart surgery possible. He has also developed more than 50 surgical instruments. Best known for his pioneering efforts in the treatment of cardiovascular diseases, he was the first to perform successful excision and graft replacement of arterial aneurysms and obstructive lesions, particularly on the carotid artery and aortic arch. A pioneer in the development of an artificial heart, he devised a booster pump and was the first to use a heart pump successfully in a patient. He also conceived the idea of lining a bypass pump and its connections with Dacron velour. His Dacron artificial arteries, which he developed to replace excised segments of diseased arteries, are now used throughout the world in the surgical treatment of diseased arteries. From experience with angiography in his patients with cardiovascular disease, he recognized definite patterns and the segmental nature of vascular disease, an observation that led to effective treatment even though the cause remained obscure. Based on

recognized anatomicopathologic characteristics of the disease, he classified arterial occlusive disease into atherosclerotic lesions affecting (1) the major branches of the aortic arch, (2) the visceral branches of the abdominal aorta, (3) the coronary arteries, and (4) the terminal abdominal aorta and its major branches. In 1953, he performed the first successful carotid endarterectomy, and thereby established the field of surgery for strokes. In 1964, Dr. DeBakey and associates performed the first aortocoronary artery bypass with autogenous saphenous vein graft. In 1968, he led a team of surgeons in performing a historic multiple transplantation procedure, in which the heart, kidneys, and one lung of a donor were each transplanted to four different recipients.

A native Louisianian, Dr. DeBakey received his academic and medical education at Tulane University in New Orleans. After completing his residency at Charity Hospital in New Orleans, he went to the Universities of Strasbourg and Heidelberg for further graduate study under Professors René Leriche and Martin Kirschner. He returned from abroad to Tulane Medical School, where he served on the surgical faculty from 1937 to 1948. From 1942 to 1946 he was on military leave, serving in the Office of the Surgeon General as Director of the Surgical Consultants' Division. He holds the rank of Colonel, Army of the United States (Reserve). One of his important contributions while on active duty in the Surgeon General's Office during World War II was his proposal of a systematic follow-up of veterans with certain medical histories, which subsequently led to the establishment of

the Committee on Veterans Medical Problems of the National Research Council and an extensive Medical Research Program by the Veterans Administration.

Recognizing the need for specialized medical centers to handle the large number of wounded servicemen who were brought back to the United States for specialized treatment and rehabilitation, he recommended development of highly specialized centers in different parts of the country for treatment of wounded veterans. This, in turn, suggested to him the desirability of applying the Center concept to civilian medicine. The Cardiovascular Research and Training Center, which he established and directed in the Texas Medical Center, was one of the first applications of this concept. This Center was unique in its multidisciplinary approach to cardiovascular research and therapy. As a result of its success, Dr. DeBakey was awarded a grant to establish the first National Heart and Blood Vessel Research and Demonstration Center.

In recognition of Dr. DeBakey's dedication to the training of young physicians, his students founded, in 1976, the Michael E. DeBakey International Cardiovascular Society, composed of members from all over the world. And in appreciation of his untiring pedagogic and investigative efforts, the Trustees of Baylor College of Medicine established the Michael E. DeBakey Center for Medical Education and Research in 1978.

Because of his unique ability to bring his professional knowledge to bear on public policy, Dr. DeBakey has earned an enviable reputation as a medical statesman. He was chairman of the

President's Commission on Heart Disease, Cancer and Stroke, and has worked tirelessly in numerous capacities to improve the national as well as international standards of health and medical care. As an influential figure in national government, he continues to devote considerable time to advisory health committees. Among his numerous consultative appointments is membership on the National Advisory Heart and Lung Council of the National Institutes of Health.

Dr. DeBakey holds membership and fellowship in the most distinguished medical and surgical societies in the world, and is a Past President of the International Cardiovascular Society, American Association for Thoracic Surgery, and the Society for Vascular Surgery, among others. He is an honorary member or fellow of a host of foreign medical societies. In 1974, he was elected an honorary member of the Academy of Medical Sciences of the Union of Soviet Socialist Republics.

Dr. DeBakey played a significant role in the establishment and development of the National Library of Medicine, and has served as a member of its Board of Regents. He was Editor of the Year Book of General Surgery for fourteen years, is now Editor of the Journal of Vascular Surgery, and has served, or is serving, on the editorial boards of numerous eminent medical and surgical journals, including the Annals of Surgery, the Journal of Cardiovascular Surgery, Surgery, Postgraduate Medicine, and the Cardiovascular Research Center Bulletin. His lifelong interest in medical publications is evidenced by the more than 1000 medical articles, chapters, and books he has authored

on various aspects of surgery, medicine, health, medical research, and medical education, as well as sociologic and philosophic discussions in these fields.

Dr. DeBakey has been honored by heads of state throughout the world. The lengthy list of awards which he has received includes the Legion of Merit, United States Army; Rudolph Matas Award in Vascular Surgery; Distinguished Service Award and Hektoen Gold Medal of the American Medical Association; Albert Lasker Award for Clinical Research; Leriche Award and Distinguished Service Award of the International Society of Surgery; St. Vincent Prize for Medical Sciences; Hunterian Award; Great Collar and Golden Medal, Prix International Dag Hammarskjöld; Gold Scalpel Award of the International Cardiology Foundation; Medical Man of the Year and Doctor of the Year, Medical World News; Gold Plate Award by the American Academy of Achievement; Henrietta Szold Award for Humanitarian Services; American Heart Association Gold Heart Award; Eleanor Roosevelt Humanities Award; Yugoslavian Presidential Banner and Sash; Union of Soviet Socialist Republics Academy of Sciences 50th Anniversary Jubilee Medal; and International Prize "La Madonnina" for outstanding contributions to science. In addition to an Honorary Doctor of Laws degree from his alma mater, he is the recipient of other honorary degrees and citations from numerous universities in this country and throughout the world. Dr. DeBakey has also been awarded the Medal of Freedom with Distinction, the highest honor a citizen can receive from the President of the United States.

STATEMENT OF

MICHAEL E. DEBAKEY, M. D.

CHANCELLOR AND CHAIRMAN OF THE DEPARTMENT OF SURGERY

BAYLOR COLLEGE OF MEDICINE

HOUSTON, TEXAS

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

March 21, 1985

Mr. Chairman and Members of the Subcommittee:

Thank you for allowing me to appear before you to discuss a subject of considerable interest to me. To place my comments in context, I would like to briefly reference my involvement in the medical specialty being addressed here today, as well as my experience with the Veterans Administration health care system.

My work in cardiovascular surgery at Baylor College of Medicine and other institutions has given me a wide perspective of the quality of medical care in this unique field. My colleagues and I have had the rewarding experience of pioneering and perfecting many surgical techniques that now are routine open heart operations. I feel a sense of pride in the fact that the Baylor College of Medicine has earned a world-wide reputation as a center of excellence for cardiovascular surgery.

My involvement in the medical care of veterans is similarly extensive. During World War II, I served in the Office of the Surgeon General, and subsequently, helped initiate a systematic follow-up study of veterans with medical problems resulting from war-related injury or illness. The Veterans Administration medical system as we know it today was established in part as a result of that study. Throughout the years since then, I have maintained what I consider a close and mutually beneficial relation with the Veterans Administration Departments of Medicine and Surgery and especially with the Veterans Administration Hospital in Houston, Texas which is affiliated with Baylor College of Medicine.

I have been particularly interested in the development of the Veterans Administration's cardiac surgery program. My experience in the field and my knowledge of this program, which I will describe in a moment, permit me to make this brief assessment.

The Veterans Administration's Departments of Medicine and Surgery provide America's veterans with cardiac surgery that meets the standards of the medical community for this specialty. In fact, the Veterans Administration's cardiac surgery program is probably one of the most closely monitored programs of this type in the United States. Attempts to measure the quality of such programs objectively will necessarily produce differing results, because of the wide variation in the patient population and selection processes, among many other factors. But in general, the Veterans Administration operates a good program, providing a vital service to patients who both need and deserve it.

I would now like to describe the program in some detail. Programs are established and operate only with the approval of the Chief Medical Director. The Chief Medical Director relies on the advice of an advisory group which has functioned in that capacity for 15 years. The advisory group, composed of both Veterans Administration and private sector cardiac surgeons and cardiologists, meets regularly every six months to review all Veterans Administration cardiac surgery programs. Based on these reviews, the group makes recommendations to the Veterans Administration in support of the cardiac surgery program. The Veterans Administration's cardiac surgery programs are located only in tertiary type Veterans Administration medical centers affiliated with a medical school. One requirement is that the medical school also must have a cardiac surgery program or share one with the Veterans Administration. The initial review of quality of care and mortality rates is done primarily at the medical center in conjunction with the medical school, with further detailed review by the advisory group. The advisory group may require an audit; make a site visit; and recommend probation, temporary suspension, or closure of a program.

The decision for a cardiac procedure must be made by the surgeon and the cardiologist, based on their very best judgment. This decision can be clear-cut in many patients but equally complex in others. This is particularly true of the high-risk patient who has shortness of breath and anginal pain with every exertion, and for whom the cardiologists and medication offer no relief.

When the patient is referred to the surgeon who informs the patient that he is a 50 percent surgical risk, and the patient says he would rather be dead than exist in that condition, the surgeon is in a dilemma when trying to make a decision. He does not want to try to play God but would like to help the patient. He also knows that operating on the patient may add to his mortality rate. His ethics cannot be questioned since he does not make any more money by operating on that patient in the Veterans Administration Hospital.

It is well known that the Veterans Administration physicians are treating an aging population. Mortality and morbidity rates are higher in older patients, as is the incidence of cardiovascular disease. Many of these patients have disease in multiple organs that contribute to the risk. Mortality rates are not necessarily an indication of a surgeon's ability and will vary from time to time with little or no control. The higher-risk patients are often referred to outstanding surgeons because of the surgeon's ability, and these patients may, of course, increase his mortality rate. Such could account for the variations in mortality rates in some of the Veterans Administration cardiac surgery programs. In the Houston Veterans Administration Medical Center cardiac surgery program, which is intimately affiliated with our medical school, the cardiac surgery mortality rate, which is very good this year, varies from year to year, with the same staff. Some of the Veterans Administration's highest mortality rates are with some of the

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contract programs. The explanation for this probably lies in the fact that this group represents higher risk, emergency cases of patients operated on locally, under contract, because their conditions do not permit transfer to a Veterans Administration medical center cardiac surgery program elsewhere.

I am sure that the Veterans Administration medical centers have the same problems of recruiting cardiac surgeons as do other medical centers. Some surgeons accept appointments at the Veterans Administration Hospital as a step to a higher salaried position or to private practice and a larger income. Veterans Administration cardiac surgeons are recruited with the assistance of the affiliated school where the surgeon is given a faculty appointment. In most instances, the cardiac surgeon is employed part-time at the Veterans Administration Hospital and part-time at the medical school, so that the same surgeon does cardiac surgery at both institutions. It is for this reason that the Veterans Administration accepts a lower productivity volume, since the surgeon maintains his expertise at both institutions. Although the turnover rate of cardiac surgeons at some Veterans Administration medical centers is higher than desired, the Veterans Administration, with the help of its affiliate, should be able to attract enough capable, dedicated, cardiac surgeons to fill its needs, especially with the increase in training of physicians today. The Veterans Administration has some physicians and surgeons who are loyal to the Veterans Administration because they enjoy institutional practice and medical school participation.

Confidentiality in the peer review process is important, if for no other reason than to prevent the circumstances that have led to this hearing. It is usually the negative that is publicized. If the mortality rate increases through no fault of the surgeon, and this increase is publicized, it reflects unfairly on the surgeon and causes patients to lose confidence in the medical center, and possibly the entire system, depending on how it is publicized. Many factors cause variations in the mortality rate. Some cardiac surgery programs in the country are selective and report their enviable mortality rates. Other programs that accept high-risk patients don't question their results, but public scrutiny and exposure are not as obvious as those of the Veterans Administration.

The Veterans Administration has reported its results frankly. Several years ago it published the early results and conclusions of Veterans Administration bypass cooperative studies. I was openly critical of the report. The Veterans Administration had, however, been honest and included results from the very beginning of its programs. Today that mortality rate has been greatly reduced, and the volume has increased to over 6,500 patients a year. Considering the condition of some of the veteran patients, the overall mortality rate of 4.7 percent for all heart surgery, including valve and bypass surgery, is not out of line.

Thank you for this opportunity to speak on behalf of the Veterans Administration's cardiac surgery programs, Mr. Chairman. I will be glad to answer any questions that I can for the Subcommittee.

New England Journal of Medicine, Nov. 22, 1984

Vol. 311 No. 21 BYPASS FOR STABLE ANGINA — VA COOPERATIVE STUDY GROUP 1333

ELEVEN-YEAR SURVIVAL IN THE VETERANS ADMINISTRATION RANDOMIZED TRIAL OF CORONARY BYPASS SURGERY FOR STABLE ANGINA

THE VETERANS ADMINISTRATION CORONARY ARTERY BYPASS SURGERY COOPERATIVE STUDY GROUP

Abstract We evaluated long-term survival after coronary-artery bypass grafting in 686 patients with stable angina who were randomly assigned to medical or surgical treatment at 13 hospitals and followed for an average of 11.2 years. For all patients and for the 595 without left main coronary-artery disease, cumulative survival did not differ significantly at 11 years according to treatment. The 7-year survival rates for all patients were 70 per cent with medical treatment and 77 per cent with surgery (P = 0.043), and the 11-year rates were 57 and 58 per cent, respectively. For patients without left main coronary-artery disease, the 7-year rates were 72 and 77 per cent in medically and surgically treated patients, respectively (P = 0.267), and the 11-year rates were 58 per cent in both groups.

A statistically significant difference in survival suggesting a benefit from surgical treatment was found in patients without left main coronary-artery disease who were subdivided into high-risk subgroups defined angiographically, clinically, or by a combination of angiographic and clinical factors: (1) high angiographic risk (three-vessel disease and impaired left ventricular function) — at 7 years, 52 per cent in medically treated patients versus 76 per cent in surgically treated patients (P = 0.002); at 11 years, 38 and 50 per cent, respectively (P = 0.026); (2) clinically defined high risk (at least two of the following: resting ST depression, history of myocardial infarction, or history of hypertension) — at 7 years, 52 per cent in the medical group versus 72 per cent in the surgical group (P = 0.003); at 11 years, 36 versus 49 per cent, respectively (P = 0.015); and (3) combined angiographic and clinical high risk — at 7 years, 36 per cent in the medical group versus 76 per cent in the surgical group (P = 0.002); at 11 years, 24 versus 54 per cent, respectively (P = 0.005). Survival among patients with impaired left ventricular function differed significantly at 7 years (63 per cent in the medical group versus 74 per cent in the surgical group [P = 0.049]) but not at 11 years (49 versus 53 per cent).

The surgical treatment policy resulted in a nonsignificant survival disadvantage throughout the 11 years in subgroups with normal left ventricular function, low angiographic risk, and low clinical risk, and a statistically significant disadvantage at 11 years in patients with two-vessel disease.

We conclude that among patients with stable ischemic heart disease, those with a high risk of dying benefit from surgical treatment, but beyond seven years the survival benefit gradually diminishes. (N Engl J Med 1984; 311:1333-9.)

IN 1975 the Veterans Administration Cooperative Study of Surgery for Coronary Arterial Occlusive Disease first reported a statistically significant survival difference in favor of surgery in the subgroup of patients with left main coronary-artery disease.[1] Two years later, in a preliminary report[2] on patients without disease in the left main artery who were followed for a minimum of 21 months, no significant difference in survival was found between medical and surgical treatment groups either overall or in angiographically defined subgroups. Subsequently, a high-risk subgroup of patients without left main coronary-artery disease, defined on the basis of clinical risk factors alone, was reported to have a significantly reduced five-year cumulative mortality with surgery.[3]

This report compares 7-year and 11-year survival after assignment to medical and surgical treatment in patients who were followed for a minimum of 107 months. Survival results for the entire group as well as for risk groups defined by angiographic and clinical measures are also presented for patients without left main coronary-artery disease. Updated survival results for patients with such disease have been reported previously.[4]

Report prepared by Katherine M. Detre, M.D., D.P.H., Peter Peduzzi, Ph.D., Timothy Takaro, M.D., Herbert N. Hultgren, M.D., Marvin L. Murphy, M.D., and George Kroncke, M.D. Address reprint requests to Dr. Detre at the Veterans Administration Medical Center, West Haven, CT 06516. For a complete listing of participants, members of the Operations and Executive Committees, Coordinating Center staff, and consultants, refer to *Circulation* 1981; 63:1329 (Appendix C).

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METHODS

The Veterans Administration cooperative study of coronary-artery bypass grafting is a randomized controlled trial of medical therapy versus medical plus surgical therapy for the treatment of patients with stable angina pectoris and angiographically confirmed coronary-artery disease. The study design, entry criteria, and base-line characteristics of the patient population have been described previously.[5] Briefly, between 1972 and 1974, 686 patients with stable angina pectoris of more than six months' duration who had been receiving medical therapy for three months and who had resting or exercise electrocardiographic evidence of myocardial ischemia were randomly assigned to medical or surgical therapy. Patients were excluded from randomization if they had had a myocardial infarction within six months or if they had refractory systemic diastolic hypertension (>100 mm Hg), left ventricular aneurysm or other serious cardiac disease, other organ-system disease making surgery inadvisable or limiting life expectancy to less than five years, unstable angina, or uncompensated congestive heart failure.

In the 1972-1974 cohort, 354 patients were randomly assigned to medical therapy, and 332 to surgical therapy, at a total of 13 clinical sites. The base-line distribution of risk factors (history, angiographic findings, electrocardiographic findings, and severity of angina) was comparable in the two treatment groups.[6]

Twenty patients randomly assigned to bypass surgery did not have an operation. Ninety-four per cent of those who underwent surgery did so within three months after random assignment. The average number of diseased vessels in surgically treated patients was 2.4, and the average number of grafts placed was 2.0. All 45 patients with single-vessel disease received at least one graft, and one fourth received multiple grafts. Of the 102 patients with two-vessel disease, 86 per cent received two or more grafts. Of the 163 patients with triple-vessel disease, 90 per cent received two or more grafts, and 37 per cent received three or more.

The overall 30-day operative mortality rate was 5.8 per cent. The incidence of perioperative myocardial infarction, calculated on the basis of the development of new Q waves, was 9.9 per cent. Vein-graft angiography was performed in 79 per cent of surgical patients (247 of 312) between 10 and 15 months after surgery, and 353 of 503 grafts placed (70 per cent) were patent at one year; 87 per cent of

patients (214 of 247) had at least one patent graft. Five years after random assignment, 52 of the 312 patients had died, and 9 had had a second operation. Graft angiography was done at five years in 156 of the 251 remaining eligible patients (62 per cent), and the patency rate was 67 per cent. The one-year and five-year graft-patency rates for the 143 patients evaluated at both times were 74 and 67 per cent, respectively.

Of 354 patients randomly assigned to medical treatment, 133 (38 per cent) had bypass surgery during an average follow-up of 11.2 years. Of the 133, 22 had left main coronary-artery disease and crossed over to surgery on an elective basis in accordance with a protocol amendment.[7,8] Thirty-five (11 per cent) of the 312 patients randomly assigned to surgery who had coronary-artery bypass grafting have had repeat grafting.

Medical therapy consisted of nitrates, beta-blockers, and other medications administered to achieve symptomatic relief of angina. At one year, 26 per cent of medically treated patients were taking nitroglycerin or nitrates only, 3 per cent were using propranolol only, and 65 per cent were taking both types of medication. The corresponding rates at five years were 27, 4, and 57 per cent. At one year and five years, 6 and 12 per cent of patients, respectively, were not taking any medication. The surgical patients took less medication than the medical patients, but their use of medication increased between one and five years. At one year, 42 per cent took no medication, 45 per cent were taking nitroglycerin or nitrates only, and the remaining 13 per cent were taking both types of medication. The corresponding rates at five years were 25, 36, and 36 per cent. At five years 3 per cent of surgical patients were taking propranolol alone.

The average follow-up time was calculated as the average time from the date of random assignment to the date of the analysis. Included in the calculation were patients who died and those known to be alive but without current follow-up data except for survival status.

Cumulative survival rates were determined by the actuarial life-table method, with death from all causes used as the end point. The survival status for patients who did not return for scheduled follow-up visits was ascertained by a retrieval system known as BIRLS (Beneficiary Identification and Records Locator Subsystem, Austin, Tex.), which is unique to the Veterans Administration network. Telephone contact was used in the few cases in which BIRLS had no patient record. The survival status was known for all but one patient. At present, 99.9 per cent of study patients have completed 9 years of follow-up, 91 per cent have completed 10 years, and 73 per cent have completed 11 years. Life-table cumulative survival rates were calculated according to the original treatment assignment (treatment policy) from the date of randomization. Differences in cumulative survival between the two treatment groups were assessed by the Mantel–Haenszel test. Thus, the 7-year statistic represents the cumulative survival experience up to 7 years, and the 11-year statistic represents the cumulative experience up to 11 years. All P values reported are two-tailed and uncorrected for multiple comparisons.

In addition to the overall treatment results, survival was compared in angiographically and clinically defined subgroups of patients without left main coronary-artery disease. The angiographically defined subgroups were identified on the basis of the number of vessels diseased (one, two, or three) and left ventricular function. The presence or absence of left ventricular functional impairment was determined according to a central reading of base-line left ventriculograms performed at the Seattle Veterans Administration Medical Center under the supervision of Dr. Karl Hammermeister. Global ejection fractions and segmental contraction abnormalities were measured. Contraction abnormalities were graded as follows: 1, no abnormality; 2, minimal hypokinesis or akinesis involving less than 25 per cent of the heart border; 3, moderate hypokinesis or akinesis of 25 to 75 per cent of the heart border; 4, dyskinesis, left ventricular aneurysm, or paradoxical wall motion; and 5, severe generalized hypokinesis or akinesis of the entire heart border. Left ventricular function was considered to be impaired if the global ejection fraction was less than 50 per cent or if the contraction grade was over 2; otherwise, left ventricular function was defined as normal. By this definition, 55 per cent of the patients had impaired function. In previous reports[1-5,9] left ventricular function was defined as abnormal if there was cardiac enlargement, elevated end-diastolic pressure (>14 mm Hg), an ejection fraction under 45 per cent, or any degree of contraction abnormality, as evaluated by the individual participants. Central readings on left ventriculograms were done in 75 per cent of the patients. Base-line readings by the individual clinics were used to provide data on left ventricular function in the other patients, according to the new definition. The combination of three-vessel disease and impaired left ventricular function was classified as a high angiographic risk. All other combinations of one-, two-, or three-vessel disease and normal or impaired left ventricular function constituted a low angiographic risk.

Subgroups with a low, middle, or high clinical risk were defined on the basis of a multivariate risk function in order to predict five-year mortality,[3,10] using four established clinical-risk variables measured at base line: the New York Heart Association classification, a history of hypertension, a history of myocardial infarction, and an ST-segment depression on the resting electrocardiogram. Other risk factors, which were not uniformly measured in all patients at base line (e.g., positive exercise test) or which had a low prevalence in the study population (e.g., congestive heart failure), could not be considered for inclusion in this risk function. Patients in the low-risk subgroup included those with none or only one of the four risk factors except for ST depression. The high-risk subgroup consisted of patients with combinations of two or three of the strongest predictors (ST depression, a history of myocardial infarction, and a history of hypertension) — i.e., those with multiple clinical risk factors. The validity of this method for the classification of patients into clinical-risk groups has been established in an independent population.[10] Reviewers and others[11,12] have criticized such "post hoc" subgroups. However, the original protocol for the 1972-1974 Veterans Administration study clearly outlined the ana-

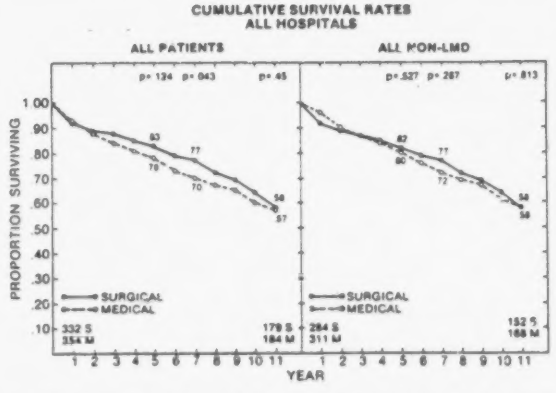

Figure 1. Eleven-Year Cumulative Survival for All Patients and for Those without Left Main Coronary-Artery Disease (non-LMD), According to Treatment Assignment. Numbers of patients at risk are given at bottom of figure. M denotes medical, and S surgical.

lytical steps for development of both the angiographic- and clinical-risk groups: "Regression analyses will be used to determine the effect [of base-line variables] on mortality and to determine groups with low and high mortality risk. . . . Analyses [life table] will be done for patients in low and high risk groups." Thus, the clinical-risk groups, defined by noninvasive base-line measures, were neither more nor less post hoc than the angiographic-risk groups, defined by such factors as left main coronary-artery disease or the combination of vessel disease and left ventricular function.

Survival analyses are based on data from all 13 hospitals, by treatment policy. In the Results we focus on the 7-year and 11-year cumulative survival rates. The five-year survival rates (early experience) are shown in the figures but are not discussed in the text, except in comparing this study with the European and the National Heart, Lung, and Blood Institute studies. All treatment comparisons are presented in reference to the medical treatment policy.

Results

Cumulative survival rates are shown in Figures 1 through 5. Patients with left main coronary-artery disease are excluded from the subgroup analyses shown in Figures 2 through 5.

Overall Results

Overall, excluding patients with left main coronary-artery disease, the treatment difference was not significant at seven years (72 per cent in the medical group versus 77 per cent in the surgical group, P = 0.267; Fig. 1). The medical and surgical survival curves converge when follow-up data are extended to 11 years (58 per cent in both groups, P = 0.813). During the first 7 years of follow-up the average annual mortality rates were 4.0 per cent for medical therapy and 3.3 per cent for surgery, including operative mortality, as compared with 3.5 and 4.8 per cent, respectively, between 7 and 11 years.

If patients with left main coronary-artery disease are included, the trends are similar, although the treatment difference in all patients was statistically significant at 7 but not at 11 years.

Vessel Disease

There was a nonsignificant trend toward improved survival with surgery at seven years in the subgroup of patients with three-vessel disease: 63 per cent with medical treatment vs. 75 per cent with surgical treatment, P = 0.061 (Fig. 2). The difference in the cumulative survival rates diminished after 7 years, resulting in only a 6 per cent difference at 11 years. At 7 years neither patients with single-vessel disease nor those with double-vessel disease had a significant difference in survival associated with treatment, although at 11 years surgically treated patients with two-vessel disease had a marginally significant disadvantage in survival (P = 0.045).

Left Ventricular Function

At 7 but not at 11 years, there was a significant difference in survival between medically and surgically treated patients with impaired left ventricular function (63 vs. 74 per cent, respectively; P = 0.049); survival rates at 11 years were 49 and 53 per cent, respectively (P = 0.249, Fig. 3). Among patients with normal left ventricular function, survival was 84 per

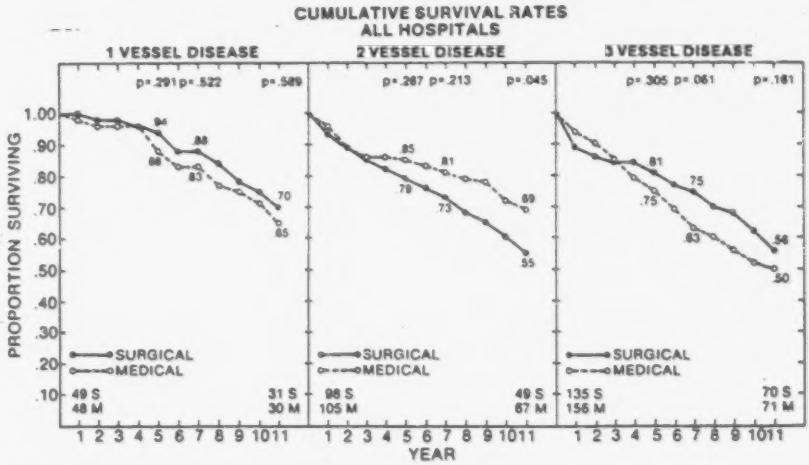

Figure 2. Eleven-Year Cumulative Survival for Patients without Left Main Coronary-Artery Disease Who Had Single-, Double-, or Triple-Vessel Disease.

Numbers of patients at risk are given at bottom of figure. M denotes medical, and S surgical.

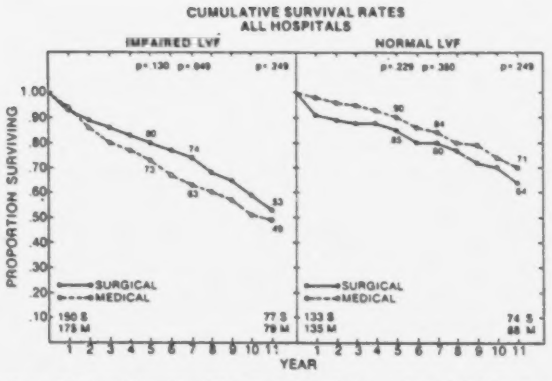

Figure 3. Eleven-Year Cumulative Survival for Patients without Left Main Coronary-Artery Disease, According to Whether Left Ventricular Function (LVF) Was Impaired or Normal.

Numbers of patients at risk are given at bottom of figure. M denotes medical, and S surgical.

cent in the medical group and 80 per cent in the surgical group at 7 years, and 71 and 64 per cent, respectively, at 11 years. These differences were not significant.

Risk Analysis

There was a statistically significant improvement in survival at seven years in surgically treated patients with a high angiographic risk (three-vessel disease with impaired left ventricular function); the rates were 52 per cent for medical treatment versus 76 per cent for surgical treatment ($P = 0.002$, Fig. 4). Although from 7 to 11 years, the marked difference in survival rates diminished from 24 to 12 per cent, the difference in cumulative survival up to 11 years remained significant ($P = 0.026$). In contrast, by 11 years, patients with a low angiographic risk had a survival rate of 68 per cent with medical therapy and 61 per cent with surgery ($P = 0.105$).

The Veterans Administration study reported a significant survival benefit with surgery at five years in patients with a high clinical risk and a significant benefit with medical therapy in patients at low risk.[3] The seven-year survival rates in the high-risk tercile were 52 per cent for the medical group and 72 per cent for the surgical group ($P = 0.003$, Fig. 5). Beyond seven years, survival remained higher in the surgical group, but the difference gradually diminished from 20 to 13 per cent by 11 years. The cumulative survival experience up to 11 years differed significantly between the two treatment groups ($P = 0.015$). In contrast, for patients in the low-risk tercile there was a 7 per cent survival disadvantage with surgical therapy at seven years (88 per cent in the medical group vs. 81 per cent in the surgical group, $P = 0.093$), which increased to 10 per cent at 11 years (73 per cent in the medical group vs. 63 per cent in the surgical group, $P = 0.066$). In the middle-risk tercile, there was no significant difference in survival at any time.

When survival in the subgroup of patients with a high angiographic risk was studied separately in the patients at low, middle, and high clinical risk, a statistically significant surgical benefit was observed only in patients who were at high risk not only angiographically but also clinically (Table 1). No significant difference in survival was observed in patients with a high angiographic risk who had a low or middle clinical risk. Although the survival experience was similar in all clinical-risk subgroups of surgically treated patients with a high angiographic risk, survival in medically treated patients decreased with increasing clinical risk at both 7 and 11 years, reflecting the strong

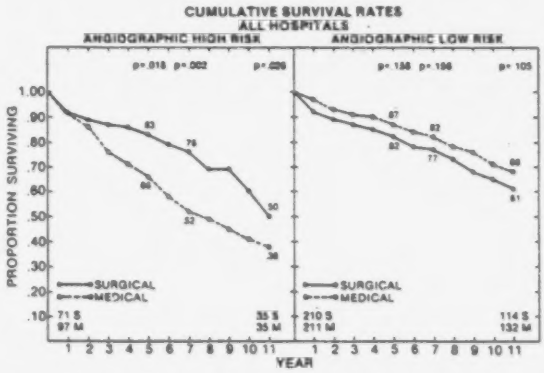

Figure 4. Eleven-Year Cumulative Survival for Patients without Left Main Coronary-Artery Disease, According to Angiographic Risk.

High risk was defined as three-vessel disease plus impaired left ventricular function, and low risk as one-, two-, or three-vessel disease plus normal left ventricular function or one- or two-vessel disease plus impaired left ventricular function. Numbers of patients at risk are given at bottom of figure. M denotes medical, and S surgical.

additional effect of clinical risk factors on the natural history of patients with a high angiographic risk.

Conversely, when survival in patients with a low angiographic risk was studied separately in the three clinical risk groups (Table 1), a disadvantage with surgery was observed at 7 and 11 years in patients who were at low risk by both measures; however, the differences were not significant. Again, the strong effect of the clinical risk factors on the natural history was evident.

Left Main Coronary-Artery Disease

The mortality rate for 48 patients with left main coronary-artery disease who were randomly assigned to surgical treatment increased after the seventh year of follow-up (data not shown). During the first seven years, the average annual mortality rate was approximately 3 per cent; thereafter, the rate increased to nearly 5 per cent. Comparison with the assigned medical group was futile, since 47 per cent of the original medical group crossed over and 44 per cent died, leaving only four patients with the original treatment assignment at seven years.

Discussion

Current survival results by treatment policy for all 13 hospitals with an operative mortality rate of 5.8 per cent (Fig. 1) indicate that for all patients and for those without left main coronary-artery disease, the cumulative survival experience up to 11 years did not differ significantly (at a two-tailed alpha level of 5 per cent) between medical and surgical treatment groups.

This overall result disregards the heterogeneous natural history of the subgroups. Consistent with the hypothesis that surgery could be advantageous for patients whose natural history was expected to be poor but would offer little or no advantage for those with a good prognosis, we found a range of treatment effects in subgroups, from a significant advantage to a borderline or nonsignificant advantage and even a disadvantage, with surgical therapy. In particular, the small group of patients who were at high risk both angiographically and by noninvasive clinical risk measures derived the greatest survival benefit from surgery (Table 1), second only to the benefit in patients with left main coronary-artery disease reported previously.[1,4] A statistically significant difference was also found when subgroups were defined by angiographic predictors alone — i.e., three-vessel disease and moderate to severe impairment of left ventricular function (Fig. 4) — or by the high-clinical-risk measure alone (Fig. 5). The surgical benefit was not significant at 11 years in the subgroups with three-vessel disease alone (Fig. 2) or with moderate to severe impairment of left ventricular function (Fig. 3), although a benefit of borderline significance appeared at 7 years ($P = 0.061$ and 0.049, respectively).

At the other end of the spectrum were the subgroups of patients with a good prognosis: those with one- or two-vessel disease (Fig. 2), normal left ventricular function (Fig. 3), a low angiographic risk (Fig. 4), and a low clinical risk (Fig. 5). With the exception of the group with two-vessel disease, for which the surgical survival rate was significantly worse ($P = 0.045$), the

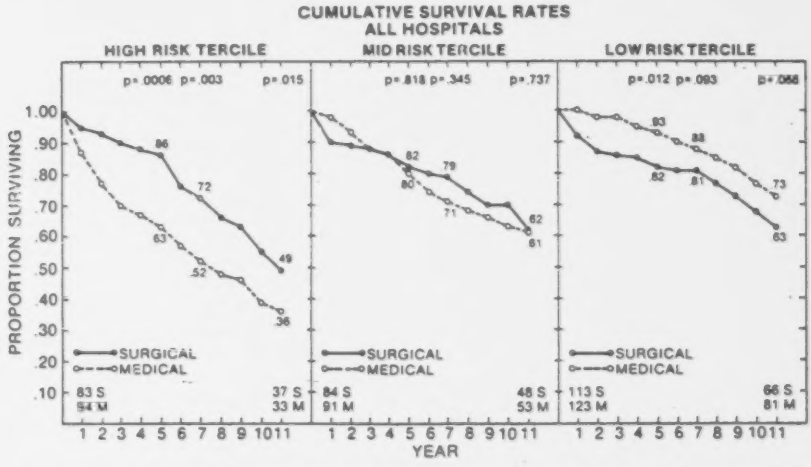

Figure 5. Eleven-Year Cumulative Survival for Patients without Left Main Coronary-Artery Disease, According to Clinical Risk. See text for definitions of high, middle, and low clinical risk. Numbers of patients at risk are given at bottom of figure. M denotes medical, and S surgical.

Table 1. Cumulative Survival Rates at 7 and 11 Years in Patients without Left Main Coronary-Artery Disease, According to Angiographic and Clinical Risk.*

		7-Year Rate (%)			11-Year Rate (%)		
	No.	Med†	Surg†	P	Med†	Surg†	P
		mean ±S.E.			mean ±S.E.		
High angiographic risk							
High clinical risk	67	36±7	76±9	0.002	24±7	54±10	0.005
Middle clinical risk	49	50±9	79±9	0.069	40±9	43±13	0.345
Low clinical risk	50	79±8	77±8	0.818	62±10	52±10	0.586
Low angiographic risk							
High clinical risk	108	67±7	70±6	0.531	46±7	46±7	0.732
Middle clinical risk	124	82±5	78±5	0.569	73±6	68±6	0.521
Low clinical risk	184	90±3	81±4	0.079	76±5	66±5	0.092

*A total of 13 patients could not be classified; 4 had missing data for the number of diseased vessels, 2 for left ventricular function, and 7 for the clinical-risk subgroup.

†Med denotes medical group, and Surg surgical group.

11-year survival disadvantage with surgical treatment was not statistically significant in the low-risk subgroups. The small survival disadvantage with surgery in these subgroups can probably be explained by the initial mortality associated with surgery.

Although the individual subgroup results reported here are weakened by the multiplicity of comparisons and the loss of power in some strata with small numbers of patients, the survival differences during the first seven years can generally be characterized by what is known about the natural history of chronic stable angina. Depending on the presence or absence of known prognostic indicators, the seven-year cumulative mortality in the medical cohort varied widely, from 10 to 64 per cent, yet mortality in the surgical cohort ranged only from 12 to 30 per cent. This resulted in a significant reduction of mortality for surgically treated patients with combinations of risk factors.

Two other large-scale randomized studies of coronary-artery bypass grafting have reported survival results: the European Coronary Surgery Study[13] and the National Heart, Lung, and Blood Institute's Coronary Artery Surgery Study (CASS).[14] Comparison of the three studies is difficult, because each enrolled different types of patients, and the periods of patient enrollment were different. For example, unlike the Veterans Administration study, CASS did not enroll patients with serious left main coronary-artery disease or with severe angina,[14] and the European study did not enroll patients with an ejection fraction under 50 per cent or with single-vessel disease.[13]

Probably in part because of differences in patient characteristics and in part because of improvement in both therapies, the five-year survival rates in medically and surgically treated patients without left main coronary-artery disease differed among the three studies. For medically treated patients the rates were 80 per cent in the Veterans Administration study, 85 per cent in the European study (calculated from reported data[13]), and 92 per cent in CASS; for surgically treated patients the rates were 82, 93 (calculated from reported data[13]), and 95 per cent, respectively. The corresponding percentage reductions in overall mortality for the surgical group as compared with the medical group were 10 per cent in the Veterans Administration study, 53 per cent in the European study, and 38 per cent in CASS. Neither the Veterans Administration result nor the CASS result was statistically significant.

The subgroups with the largest benefit from surgical treatment in the Veterans Administration study have no direct counterparts in the other two studies. The subgroup of patients in CASS that resembles most closely the Veterans Administration high-angiographic-risk group, the subgroup with three-vessel disease and an ejection fraction under 50 per cent, had a nearly significant benefit from surgery at five years ($P = 0.063$). On the other hand, the European study, which examined the joint effect of clinical and angiographic risk factors, concluded that "in the absence of [clinically defined] prognostic variables in patients with either two- or three-vessel disease the outlook is so good that early surgery is unlikely to increase the prospect of survival." Thus, all three studies point toward a possible surgical benefit in the presence of high risk — i.e., multiple risk factors that indicate a poor prognosis measured by angiography or by other means.

With data now available from the extended follow-up in the Veterans Administration study, long-term results of therapy can be studied. So far, the most important observation is that the mortality rate in all surgical subgroups increased between 7 and 11 years. During the first seven years of follow-up, the average annual mortality rate was 3.3 per cent for all surgically treated patients without left main coronary-artery disease, as compared with a rate of 4.8 per cent during the next four years. For medically treated patients without left main coronary-artery disease, the rates were 4.0 and 3.5 per cent, respectively. The increased mortality in the surgical group is consistent with the findings of the Montreal Heart Institute investigators who followed a series of patients for 12 years. They found that although angina had improved in 80 per cent of patients at 6 years, it remained improved in only 47 per cent of the 12-year survivors.[15] The annual graft-closure rate at 7 to 12 years was 5.2 per cent — more than double the 2.1 per cent rate between 1 and 7 years.[16] The Montreal Heart Institute predicted that because of late graft changes, long-term relief of symptoms and survival may be compromised. Our observation of accelerated mortality after seven years in surgically treated patients but not in those receiving medical treatment supports this prediction.

In conclusion, we found that in the Veterans Administration study population bypass surgery did not significantly improve overall survival among patients without left main coronary-artery disease. However, a survival benefit with surgery was observed at five to seven years in subgroups of patients with multiple

clinical and angiographic risk factors. The observed benefit with surgery diminished gradually when follow-up was extended to 11 years.

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EXERCISE-INDUCED ISCHEMIA IN MILDLY SYMPTOMATIC PATIENTS WITH CORONARY-ARTERY DISEASE AND PRESERVED LEFT VENTRICULAR FUNCTION

Identification of Subgroups at Risk of Death during Medical Therapy

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Abstract To determine prospectively whether the severity of reversible left ventricular ischemia provides prognostic information in mildly symptomatic patients with coronary-artery disease and preserved left ventricular function at rest (ejection fraction greater than 40 per cent), we studied 117 patients by means of exercise electrocardiography and radionuclide angiography. No patient had stenosis of the left main coronary artery. Mortality during subsequent medical therapy was significantly associated (by univariate life-table analysis) with three-vessel coronary-artery disease and the magnitude of the ejection fraction during exercise. In patients with three-vessel disease who had both ST-segment depression of 1 mm or more and a decrease in ejection fraction during exercise, in association with an exercise tolerance of 120 W or less, the probability of survival at four years was only 71±11 per cent (S.E.). All deaths occurred in this subgroup. Thus, objective evidence of left ventricular ischemia during exercise and exercise capacity identify one subgroup of minimally symptomatic patients with three-vessel disease with an excellent prognosis and another subgroup at relatively high risk of dying during subsequent medical therapy. (N Engl J Med 1984; 311: 1339-45.)

SEVERAL recent multicenter trials have identified factors predictive of poor prognosis in coronary-artery disease during medical therapy. These factors include left ventricular dysfunction and stenosis of either the left main coronary artery or all three major epicardial coronary arteries.[1-7] Although survival is reduced in mildly symptomatic patients with preserved left ventricular function who have three-vessel disease, as compared with patients with one- or two-vessel disease,[5,7,8] the effect of surgery on the natural history of the patients with three-vessel disease is equivocal. The Coronary Artery Surgery Study (CASS) demonstrated no difference in survival between medically and surgically treated patients with three-vessel disease and normal left ventricular function,[7] but the European Coronary Surgery Study Group reported improved survival in such patients treated surgically.[6] The disparity in these results arose solely from the fact that the medically treated patients with three-vessel disease in the European study had a

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Multivariate discriminant analysis of the clinical and angiographic predictors of operative mortality from the Collaborative Study in Coronary Artery Surgery (CASS)

The Collaborative Study in Coronary Artery Surgery (CASS) is a large multi-institutional study of the medical and surgical treatment of coronary artery disease (CAD). Fifteen cooperating institutes have carried out isolated coronary artery bypass grafting (CABG) on 6,176 patients from August, 1975, through December, 1978. The operative mortality (OM) was 2.3%. In an effort to better understand the clinical and angiographic characteristics predictive of OM, we have done a multivariate discriminant analysis of variables associated with OM. Numerous clinical and angiographic variables were selected from the CASS data file and evaluated in a univariate manner for their relationship to OM. Twenty of these variables were then selected for multivariate discriminant analysis. Clinical variables of most predictive value were age, female sex, increased heart size, and congestive heart failure (CHF). Angiographic variables of importance included left ventricular wall motion abnormalities, and left main coronary disease (LMCD). The priority of operation (elective, urgent, or emergent) was also associated with OM. Six variables that contained the most predictive information were selected by discriminant analysis for a group of 6,176 patients who had isolated bypass operations. In descending order of importance they were age, left main coronary artery stenosis ≥90%, female sex, left ventricular wall motion score, left ventricular end-diastolic pressure (LVEDP), and râles. Five other groups or subgroups of patients were also analyzed in a similar manner. There is a strong association of OM with advanced age, female sex, and variables associated with left ventricular dysfunction. The risk of OM for an individual patient may be estimated with the use of these clinical and angiographic characteristics.

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Various operative procedures are now available for the treatment of coronary disease and its complications. The operative mortality (OM) associated with aorta-coronary saphencus vein bypass grafting has steadily diminished over the past decade so that the patient with symptomatic coronary disease and preserved left ventricular function can be operated upon with an overall mortality in the range of 1% to 3%. There are categories of patients in which the OM is much greater.[1, 2] Medical therapy may be more appropriate for these patients. Without a full understanding of those factors which correctly identify the high-risk patient, it is not possible to make the best therapeutic decision for each patient. A good deal of information is now available about factors which increase surgical risk. Individual risk factors have been recently reviewed by use of the clinical and angiographic data available from the CASS registry.[3] Surgical risk, however, is probably

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never determined by a single factor. Usually a combination of factors will determine the overall risk for the patient. The technique of multivariate discriminant analysis allows the investigator to select that combination of variables which offers the greatest amount of predictive value and provides information about the relative importance of each factor.[4]

CASS is a multi-institutional study of the medical and surgical treatment of coronary artery disease (CAD). The data file of CASS contains detailed information about the clinical, angiographic, and surgical characteristics of patients enrolled in the study. This information may be related to the results of surgical therapy, and in this way those variables or combination of variables which are most closely related to the surgical outcome are identified.

In any multi-institutional study, there is inherent site-to-site variability. Although major efforts have been made to make data collection uniform from site to site, some variability remains. More important for this study is the variability in the characteristics of the patients that are selected for surgical treatment and the variability in the results of operation between institutions. A report of the predictors of surgical mortality must deal with this inter-institutional variation in patient selection and surgical results. In order to accomplish this, we have analyzed the patients operated upon at each site. From the baseline characteristics of the surgical patients at each site the expected mortality, based upon the performance of all sites, has been determined. Variation between observed and expected mortality has been determined and used as a basis for between-site comparison of operative mortality (OM). With the use of this technique we have been able to fairly evaluate OM for each institution.

This paper will present the information available in the CASS data registry related to surgical mortality by the technique of multivariate discriminant analysis. It is hoped that this information will be helpful to clinicians who make these therapeutic decisions.

Methods

Patient population. The Collaborative Study in Coronary Artery Surgery (CASS) is a multi-institutional research program consisting of a randomized trial of the medical and surgical treatment of CAD and a large registry containing patients undergoing diagnostic evaluation including coronary arteriography for the presence of suspected CAD. This report includes 7,139 patients at the fifteen clinical sites who had surgical treatment for CAD in the period August, 1975, through December, 1978. The surgically treated patients were selected from a total group of 12,079 men and 2,278 women who had CAD, defined as ≥70% luminal diameter narrowing of a major coronary artery.

Data management. The baseline data were collected by physicians and trained data technicians at the time the patient was hospitalized for coronary arteriography. All data were recorded on standard CASS forms which were specifically designed and tested for use in this study. Physicians and technical personnel were trained in the use of these forms and detailed instructions were available for reference. Frequent meetings were held prior to and during the data collection period in an effort to standardize the reporting of data. Special efforts were made to obtain uniform reporting of angiographic data. Meetings were held with angiographic directors and technicians to improve the quality of the angiographic examinations. These precautions have minimized inter-institutional variation in data acquisition. Data from each site were transmitted to the data coordinating center by computer terminals (Datapoint Model 110, Datapoint Corporation, San Antonio, Texas) programmed to detect errors of data entry. This method of automated data transmission has resulted in a very low error rate.[5]

Data base. Extensive historical, physical, and laboratory information was collected on each patient at the time of entry into CASS. These baseline data were recorded on eight different forms. The authors selected from the baseline data those variables which might be related to surgical outcome. Each of these variables was analyzed univariately to determine the relationship of the variable to OM. The variables shown to be related to OM were then used in the multivariate discriminant analysis for the prediction of surgical mortality.

Definitions used were those of the CASS protocol. Angina was graded according to the classification of the Canadian Cardiovascular Society.[6] Categories were added for angina unrelated to exertion and for unstable angina (change in pre-existing pattern within 2 months of entry). A history of myocardial infarction required that the patient had been informed by a physician of a definite infarct. The priority of the operative procedure was assigned by the surgeon. Emergency procedures were performed on the day of coronary arteriography in most cases. Urgent procedures were performed within 6 days of arteriography. Operative deaths were defined as those that occurred after the operation was commenced and before discharge from the hospital.

Clinical variables related to left ventricular failure were evaluated because of the widely known association of poor left ventricular function with OM. These included a history of congestive heart failure (CHF),

pulmonary râles, and the use of digitalis and diuretics. In addition, a CHF score was developed which included the number of positive responses to a history of CHF, use of diuretics, use of digitalis, and the presence of pulmonary râles on the admission physical examination (possible score 0-4).

Coronary arteriography was performed by either the brachial or femoral technique. Several views of each coronary vessel were used for analysis. The extent of arterial stenosis, defined as the percent of maximal luminal narrowing, was recorded for each of 27 coronary segments. In this study ≥70% luminal narrowing of a major coronary artery and ≥50% narrowing of the left main coronary artery (LMCA) are considered important lesions. A lesser degree of narrowing is classified as minimal disease.

Left ventricular cineangiography was carried out in the 30 degree right anterior oblique (RAO) view. The RAO ventriculogram was divided into five segments: anterobasal, anterolateral, apical, diaphragmatic, and posterobasal. The systolic motion of each of these segments was recorded and scored numerically as follows: normal 1, moderate hypokinesia 2, severe hypokinesia 3, akinesia 4, and dyskinesia 5. Aneurysmal segments were assigned a score of 6. A normal left ventricle was therefore scored as 5; it is theoretically possible to record a score of 30. The left ventricular end-diastolic pressure (LVEDP) measured prior to angiography was available in 6,176 patients.

A myocardial jeopardy index was developed to relate the functional status of left ventricular wall segments to disease in the major artery supplying those segments. Left ventricular wall segments which move normally or are hypokinetic are assumed to be composed of viable myocardial tissue and are at risk of infarction if the artery supplying the segments is stenotic (stenosis ≥70%). Akinetic or dyskinetic regions are assumed to represent nonfunctional tissue, which is therefore not at risk of infarction. The anterobasal, anterolateral, and apical segments are considered as a unit which is assumed to be supplied by the left anterior descending coronary artery. The diaphragmatic and posterobasal segments constitute a second unit which is assumed to be supplied by the right coronary artery in a right dominant system or by the circumflex artery in a left dominant system. By considering the segmental motion and degree of stenosis for each of these two units, one can obtain a jeopardy score from 0 to 2 units.

Aorta-coronary bypass grafting was performed by use of the routine techniques of anesthesia, myocardial preservation, and graft anastomosis practiced at each individual institution. In addition to coronary artery bypass grafting (CABG), 509 patients had additional cardiac procedures. Such procedures included mitral valve replacement, ventricular aneurysm resection, and ventricular plication. These patients were included in specified portions of the analysis. For patients who have had more than one coronary bypass operation, only the results of the first operation after entering CASS were analyzed.

Analysis of data by site. There were fifteen CASS sites which contributed data for this analysis. There was, of course, variation in patient characteristics and in selection of patients for surgical treatment. In addition there were clear differences in OM between some individual sites and others and between individual sites and the group as a whole. It is important to evaluate intersite differences in surgical results. It is CASS' policy to preserve the anonymity of individual sites in reporting performance.

Since there are differences in the characteristics of patients undergoing operation at different sites, OM must be adjusted for these differences in the operated patients if valid comparisons of between site variation in OM are to be made. From the multivariate stepwise discriminant analysis carried out on the total group of patients, the clinical and angiographically derived variables that are associated with OM were identified. Patients undergoing operation at each site were evaluated for the presence or absence of these predictive variables. From this analysis the number of expected surgical deaths for each site has been derived. The observed number of deaths (O) has then been divided by the expected number of deaths (E) to derive an O/E ratio. An O/E ratio <1.0 indicates a lower OM than the average after adjusting for pertinent variables for the total group of patients. An O/E ratio >1.0 is indicative of higher than expected mortality. This procedure of adjusted OM allows valid comparison of intersite differences in surgical results.

Statistical analysis. This paper utilizes the technique of multivariate discriminant analysis to obtain a better understanding of those factors that are important in determining the risk of CABG operations. Briefly, discriminant analysis is used to develop a rule to distinguish between two or more groups, in this case, between those who survive and those who do not survive coronary artery operations. The first step in this process is the examination of variables that measure characteristics which are expected to differ in the two groups (survivors and nonsurvivors). In this study, a large number of clinical and angiographic variables were selected from the CASS data file and examined for their univariate relationship to OM. The 20 variables iden-

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Table I. *Clinical and angiographic predictors of operative mortality*

Clinical characteristics
Age
Sex
Angina classification
Canadian Cardiovascular Society Class I to IV
Unstable angina
Manifestations of heart failure
History of heart failure
Pulmonary rales
Use of digitalis
Use of diuretics
Congestive heart failure score (0-4)
Coronary artery anatomy
No. of vessels with ≥70% stenosis
Left main coronary artery stenosis (none ≤50%, mild 50%-70%, moderate 75%-89%, severe ≥90%)
Left ventricular function
Cardiac enlargement on chest roentgenogram (slight, moderate, marked)
Cardiothoracic ratio ≥0.50
Left ventricular end-diastolic pressure
Wall motion score (5-30)
Myocardial jeopardy index (0-2)
Left ventricular enlargement—angiogram
Surgery
Priority of surgery (elective, urgent, emergent)
Aneurysmectomy and/or plication
Mitral valve replacement
No. of operated vessels

tified as related to OM and subsequently used in the discriminant analysis are listed in Table I.

The principle of discriminant analysis is to select the linear combination of variables which separates the two groups as much as possible. The process is carried out in a stepwise manner so that at each step in the process, the variable which contains the most discriminating power, when added to the variables already selected for the model, will be identified. The process stops when the remaining (unselected) variables all have additional discriminating ability that is *not* statistically significant ($p > 0.05$). In building the model, discriminant analysis takes account of the relationships among the variables. The relative importance of each discriminating variable is indicated by the F statistic. Variables with an F statistic ≥ 7 ($p < 0.01$) are included in this report.

The results of this multivariate discriminant analysis of the predictors of OM are presented for several clinical groups.

Group I. All operated patients. This group includes all 6,652 patients undergoing coronary artery operations and associated cardiac operations for whom complete data for the variables listed in Table I were available. There were 38 patients who had mitral valve operations and 345 patients who had surgical treatment of a ventricular aneurysm. The surgical priority (elective, urgent, emergent) was not included as a variable in this analysis.

Table II. *Operative morality for groups*

Group	No of pts.	Description	OM (%)
I	6,652	All operated pts.	2.9
II	6,176	All CABG only pts.	2.3
III	4,913	Elective CABG pts.	1.7
IV	1,263	Urgent-emergent CABG pts.	4.4
V	4,303	CABG only, <60 years	1.4
	1,873	CABG only, ≥60 years	4.2
VI	5,197	Men CABG only	1.8
	979	Women CABG only	4.5

Legend: OM, Operative mortality. CABG, Coronary artery bypass grafting.

Table III. *Group I: All patients undergoing operation, including other operations (N = 6,652, OM = 2.9%)*

Variable	F to enter
CHF score	79.7
Mitral valve surgery	48.4
Other cardiac surgery	36.9
Age	33.3
LMCD ≥90%	26.2
Heart enlargement	21.4
Aneurysm surgery	21.0
Sex	18.4
LVEDP	14.0
Severity of heart enlargement on chest x-ray film	10.9

Legend: OM, Operative mortality. CHF score, Congestive heart failure. LMCD, Left main coronary disease (stenosis). LVEDP, Left ventricular end-diastolic pressure.

Group II. All CABG operations. This group of 6,176 patients had CABG as their only surgical procedure. Patients with all three surgical priorities are included and surgical priority is not considered as a variable.

Group III. Elective CABG operations. This group includes the 4,913 patients who underwent elective CABG without additional surgical procedures.

Group IV. Urgent or emergent CABG operations. This group includes the 1,263 patients who had emergent or urgent CABG without other surgical procedures.

We have also done an analysis of the patients in Groups II, III, and IV divided by sex. Last, we have evaluated the influence of age by doing an analysis of patients in Group II above and below the age of 60 years.

Table IV. *Group III: All patients having isolated CABG (N = 6,176, OM = 2.3%)*

Variable	F value
Age	47.2
LMCD ≥90%	34.5
Sex	19.7
LV wall motion score	20.0
LVEDP	10.4
Râles	7.8

Legend: CABG, Coronary artery bypass grafting. OM, Operative mortality. LMCD, Left main coronary disease (stenosis). LV, Left ventricular. LVEDP, Left ventricular end-diastolic pressure.

Table V. *Group III: Patients having elective CABG (N = 4,913, OM = 1.7%)*

Variable	F value
Sex	21.0
Age	14.4
LV wall motion score	9.7

Legend: CABG, Coronary artery bypass grafting. OM, Operative mortality. LV, Left ventricular.

Results

The 20 variables that were statistically related to OM ($p < 0.05$) are listed in Table I. These variables were utilized in the stepwise multivariate discriminant analysis to determine the group of variables which best predicted OM. The OM for the total group of patients and various subgroups is given in Table II. It ranged from a low of 1.4% for patients under the age of 60 years to 4.5% for women having isolated CABG. For Group I (all patients operated upon) the statistically significant variables are shown in Table III. They have been ordered by the value of the F statistic, which is a rough indicator of the relative predictive power of each variable. In addition to age and sex, we can categorize the variables into several groups including additional operation (mitral valve replacement, other cardiac operation, and aneurysm operation), decreased left ventricular performance (the presence and severity of heart enlargement on the chest roentgenogram and LVEDP), heart failure as indicated by CHF score, and the presence of severe disease of the left main coronary artery (LMCD). In addition to age and sex, we can categorize these variables into three groups: the performance of additional operations (mitral valve replacement, other operation, aneurysm operation), decreased left ventricular performance (left ventricular enlargement and its severity on chest roentgenogram, and LVEDP), and the presence of heart failure (CHF score and râles). One variable is related to coronary anatomy (LMCD ≥ 90%).

Table VI. *Group IV: Urgent and emergent CABG (N = 1,263, OM = 4.4%)*

Variable	F value
Age	17.5
LMCD ≥90%	13.8
Râles	13.3
No. of jeopardized segments	10.2
No. of operated vessels	9.9

Legend: CABG, Coronary artery bypass grafting. OM, Operative mortality. LMCD, Left main coronary disease (stenosis).

Table VII. *All patients having CABG*

Age			
<60 years		>60 years	
N = 4,303 OM = 1.4%		N = 1,873 OM = 4.2%	
Variable	*F value*	*Variable*	*F value*
CHF score	17.0	LMCD ≥ 90%	33.7
Sex	14.4	Unstable angina	9.9
		LVEDP	9.7

Legend: OM, Operative mortality. CHF, Congestive heart failure. LMCD, Left main coronary disease. LVEDP, Left ventricular end-diastolic pressure.

The same type of analysis for all patients undergoing isolated CABG is presented in Table IV. In this group of 6,176 patients (OM 2.3%), age, sex, and severe LMCD are the most important variables. A high left ventricular wall motion score, elevated LVEDP, and the presence of râles, all indicative of poor left ventricular function, also entered as predictive variables.

Surgical priority (elective, urgent, emergent) is an important discriminant variable and has therefore been analyzed separately. We have divided the group into the 4,913 patients who had elective CABG in Table V and those who had urgent or emergent CABG in Table VI. In the patients having elective operations, OM was low (1.7%). The age and sex are important predictors of risk, followed by left ventricular wall motion score. In the urgent-emergent group, the OM increased to 4.4%. Age, LMCD ≥90%, and râles entered whereas left ventricular wall motion score dropped out and the number of operated vessels and jeopardized segments entered as significant variables.

Since age is related to OM in most subgroups, we carried out the analysis for all patients who had isolated CABG above and below the age of 60 years (Table VII). There were 4,303 patients under the age of 60 years who had an OM of 1.4%. In this group, sex and CHF score were the important variables. In the 1,873 patients 60 years of age or older with an OM of 4.2%,

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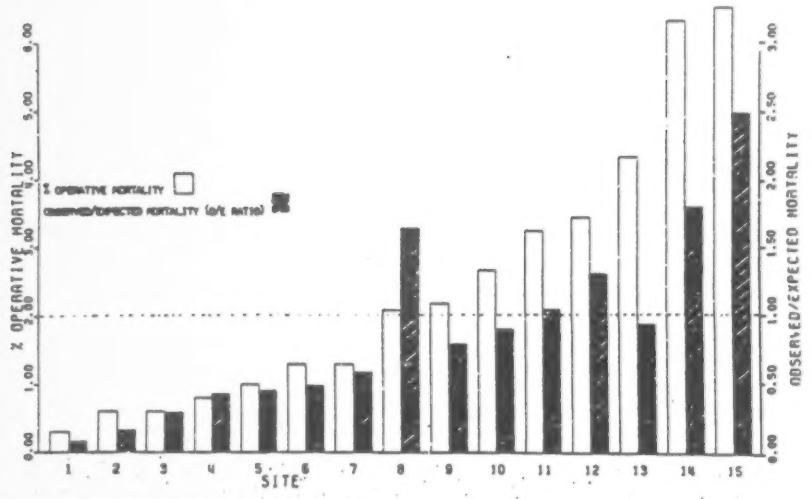

Fig. 1. All cases of isolated coronary artery bypass grafting. The operative mortality *(open bars)* and observed/expected mortality ratio *(O/E) (shaded bars)* for individual participating sites are shown. When the O/E is <1.0, the operative mortality for the patient population at that site is less than expected when compared to the average operative mortality predicted for all sites. When O/E is >1, the operative mortality at the site is greater than anticipated for the patients operated upon at this site.

LMCD ≥90%, LVEDP, and unstable angina were the important variables.

Finally, we evaluated predictors of OM separately for men and women by dividing them into three groups: total, elective, and urgent-emergent (Table VIII). OM was at least twice as high for women in all groups. Similar variables were predictive in men as those for the group as a whole (Table III). For the total group of women, only LMCD ≥90% and LVEDP were significant predictive variables. LVEDP entered as the single variable related to OM in the group having elective operations. The presence of râles was the only variable entering for the 256 women who had urgent or emergent CABG.

We have also looked at the OM by year for the entire group of 6,176 patients who had CABG without additional operative procedures. Between Aug. 1, 1975, and Dec. 31, 1978, the calendar year mortality was 2.1% in 1975, 2.1% in 1976, 2.3% in 1977, and 2.6% in 1978. There was no statistically significant difference in OM by year.

The OM and observed/expected mortality ratio (O/E) by site is shown in Fig. 1 and Table IX. The institutions and number of patients operated upon at each site are not identified to preserve the anonymity of the institutional results. The OM varied from 0.3% to 6.6%. The O/E ratio varied from 0.16 (site 1) to 2.52 (site 15). The mean OM for all sites was 2.3%. Seven sites had an OM ≤2.3% and eight sites had an OM >2.3%. An O/E ratio = 1.0 indicates that a site has an OM which is average for the group as a whole when the clinical and angiographic characteristics of patients undergoing operation at that site are taken into consideration using multivariate discriminant analysis (CABG only, Table IV). As shown in Fig. 1, ten sites had an O/E ≤1.0 and six sites an O/E ≤0.5. Site 13, with the third highest OM (4.4%) had an O/E = 0.96 indicating a lower than expected OM considering the characteristics of patients operated upon at that institution. Site 14, on the other hand, had an O/E = 1.8 indicating that the OM is greater than expected for the group of patients having CABG at that institution.

Discussion

In this study, we have utilized the technique of multivariate discriminant analysis in an effort to identify those clinical and angiographic variables which are related to the risk of CABG operations. Up until this time, there have been relatively few efforts to assess the factors which influence CABG surgical risk. Much of

Table VIII, A. *CABG in men*

Total group		*Elective*		*Urgent-emergent*	
N = 5,197 OM = 1.8%		N = 4,190 OM = 1.4%		N = 1,007 OM = 3.8%	
Variable	*F value*	*Variable*	*F value*	*Variable*	*F value*
Age	32.5				
LMCD ≥ 90%	26.1	Age	15.4	CHF score	21.4
LV wall motion score	18.4	LV wall motion score	10.6	LMCD ≥ 90%	8.4
CHF score	9.9			LV enlargement—angiogram	8.0

Legend: OM, Operative mortality. LMCD, Left main coronary disease (stenosis). LV, Left ventricular. CHF, Congestive heart failure.

Table VIII, B. *CABG in women*

Total group		*Elective*		*Urgent-emergent*	
N = 979 OM = 4.5%		N = 723 OM = 3.6%		N = 256 OM = 7.0%	
Variable	*F value*	*Variable*	*F value*	*Variable*	*F value*
LMCD ≥ 90%	10.8	LVEDP	8.4	Rales	13.9
LVEDP	9.2				

Legend: OM, Operative mortality. LMCD, Left main coronary disease (stenosis). LVEDP, Left ventricular end-diastolic pressure.

Table IX. *All patients having isolated CABG: Operative mortality and observed mortality/expected mortality*

Site	*OM*	*O/E*
1	0.3	0.08
2	0.6	0.16
3	0.6	0.29
4	0.8	0.43
5	1.0	0.45
6	1.3	0.49
7	1.3	0.59
8	2.1	1.66
9	2.2	0.80
10	2.7	0.91
11	3.3	1.07
12	3.5	1.33
13	4.4	0.96
14	6.4	1.83
15	6.6	2.52

Legend: OM, Operative mortality. O/E, Operative mortality/expected mortality.

the information regarding specific risk factors has been derived from studies of highly selected patient groups. Statistical techniques usually have been limited to univariate methods, so that the inter-relationship of various risk factors is uncertain.

Oldham and associates[7] identified several risk factors in a series of 276 patients who had coronary artery operations before mid-1972. Patients who had mitral valve replacement or ventricular resection were included in the analysis. The overall OM rate was 10.5% in this early study. The group of nonsurvivors had impaired ventricular function as evidenced by increased arterial venous oxygen difference, elevated LVEDP, reduced ejection fraction, and dyskinetic contraction patterns. Stenosis of the LMCA and mitral insufficiency were additional risk factors. Clinical characteristics were not useful in assessing a patient's surgical risk in this study.

Hammermeister and Kennedy[8] studied the association of 10 preoperative variables with operative death that occurred in seven of 138 patients. The age and sex distributions of the study group were not provided. Included in the analysis were seven patients who had valve replacement at the time of the coronary artery operation. The only variables predictive of OM were those which reflected poor left ventricular performance. Nonsurviving patients had increased left ventricular end-diastolic pressure and volume and reduced ejection fraction. Age, functional classification, exercise capacity, the extent of coronary artery lesions, and cardiac index were not significantly different in survivors and nonsurvivors. Given the relatively small sample size, however, it cannot be concluded that these variables have no bearing on OM.

Discriminant analysis was used by Loop and associ-

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ates[2] to examine factors associated with the operative death of 60 patients who had an aorta-coronary bypass operation before 1973. The group of nonsurvivors was compared to a group of 1,188 patients who were discharged from the hospital following operation in 1973. The age range and sex distribution of the study population were not reported. CHF was the best discriminant of OM. Heart failure was defined to include elevated LVEDP in addition to symptoms and signs of ventricular failure. Global left ventricular contraction abnormality was the next best discriminating factor. Less discriminating but significant factors were emergency operation, LMCD, cardiomegaly, and the number of diseased coronary arteries. The patient's age was not a significant factor. The influence of the patient's sex was not examined.

Impairment of left ventricular function manifested clinically or demonstrated at cardiac catheterization has been shown to be associated with increased OM in previous studies. Stenosis of the LMCA has also been found to be an important predictor of surgical mortality when this lesion is considered as a separate variable. It is somewhat surprising that advanced age has not been identified as a risk factor. The importance of the patient's sex in predicting OM has not frequently been considered and was not examined in the reports reviewed here. The CASS study with its large number of patients and extensive computerized data bank has allowed us to evaluate many factors associated with OM. This analysis also has identified variables related to left ventricular dysfunction and the presence of severe stenosis of the LMCA as associated with increased OM. In addition, the importance of advanced age and female sex has been clearly demonstrated. These important relationships may not have been clear previously because of the relatively small number of women and elderly patients contained in prior operative series. We have also confirmed the large difference in OM between elective and urgent or emergent surgical procedures and the high OM that is associated with operations for the complications of ischemic heart disease. The relative unimportance of the severity of the chest pain syndrome in relationship to OM is demonstrated by the fact that unstable angina entered in only one subgroup. When the LMCA was not severely stenosed, the number of vessels diseased did not enter as a discriminant variable and the number of vessels bypassed was only of importance in patients having urgent-emergent operations. A low ejection fraction has frequently been associated with increased OM, as previously noted. In the CASS registry, the ejection fraction was shown not to be as useful as the wall motion score as a univariate predictor of OM.[3] Since the ejection fraction was not available in 20% of patients, this variable was not included in the discriminant analysis.

The large variation in OM by site from 0.3% to 6.4% was unanticipated. An OM of 2.3% overall for unselected patients undergoing isolated CABG operations is similar to the results of many institutions. Five of the institutions had an OM $\leq$1.0%. Considering that the group of patients operated upon at each site contains all isolated CABG operations, including urgent and emergent cases, this low OM is an example of outstanding surgical success. At each of these five institutions, the O/E ratio was $\leq$0.45 indicating that the actual OM was less than half the expected OM based on the clinical and angiographic characteristics of the patient population at each site. At site 1, the O/E ratio reached a remarkably low 0.08.

In some instances, an apparently high OM can be explained by the high-risk nature of the patient group. At site 13, although the OM of 4.4% is third highest for all sites, the O/E ratio of 0.96 indicates that the expected OM at that site is also high and these surgical results are close to the mean for all sites. On the other hand, the high OM at sites 12, 14, and 15 cannot be explained by a high-risk group of surgical patients, and the relatively low OM at site 8 (2.1%) is too high based on their population of surgical patients. From these facts it is clear that a careful analysis of patient population and the determination of O/E for OM is essential to make a meaningful comparison of OM between institutions.

It is our hope that the results of this study will help physicians make decisions for medical or surgical therapy in individual patients. Although we recognize that the surgical results of an individual institution will always be of paramount importance in making surgical decisions, the information derived from a large cooperative series may be of additional help and is more representative of the current national experience. This is most true when considering those variables which can be evaluated only with a large number of patients. The availability of a large series such as this report from CASS takes on greater importance as the overall OM decreases and the differences in OM between subgroups become small.

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Cooperating clinical sites

University of Alabama in Birmingham: Richard O. Russell, Jr., M.D.,* William J. Rogers, M.D., Albert Oberman, M.D., and Nicholas T. Kouchoukos, M.D. *Albany Medical College:* Julio A. Sosa, M.D.,* Martin F. McKneally, M.D.,* Joseph MacIlduff, M.D., Thomas Older, M.D., and Eric K. Foster, M.D. *Loma Linda University:* Melvin P. Judkins, M.D.,* and Joan Coggin, M.D. *Boston University:* Thomas J. Ryan, M.D.,* David Faxon, M.D., Laura Wexler, M.D., Robert L. Berger, M.D., and Carolyn H. McCabe, B.S. *Marshfield Clinical Foundation for Medical Research and Education:* William Myers, M.D.,* Richard D. Sautter, M.D.,* John N. Browell, M.D., Dieter M. Voss, M.D., and Robert D. Carson, M.D. *Massachusetts General Hospital:* J. Warren Harthorne, M.D.,* W. Gerald Austen, M.D.,* Robert Dinsmore, M.D., Frederick Levine, M.D., and John McDermott, M.D. *Mayo Clinic and Mayo Foundation:* Robert L. Frye, M.D.,* Hugh C. Smith, M.D., Ronald E. Vlietstra, M.D., and Richard Fulton, M.D. *Miami Heart Institute:* Arthur J. Gosselin, M.D.,* Parry B. Larsen, M.D., and Paul Swaye, M.D. *Montreal Heart Institute:* Martial G. Bourassa, M.D.,* Bernard R. Chaitman, M.D., Claude Goulet, M.D., and Jacques Lesperance, M.D. *New York University:* Ephraim Glassman, M.D.,* and Michael Scholoss, M.D. *St. Louis University:* George Kaiser, M.D.,* J. Gerard Mudd, M.D.,* Robert D. Wiens, M.D., Hendrick B. Barner, M.D., John E. Codd, M.D., Denis H. Tyras, M.D., and Vallee L. Willman, M.D. *St. Luke's Hospital Center:* Harvey G. Kemp, Jr., M.D.,* and Airlie Cameron, M.D. *Stanford University:* Edwin Alderman, M.D.,* James F. Silverman, M.D.,* and Edward B. Stinson M.D. *Medical College of Wisconsin:* Felix Tristani, M.D.,* Harold L. Brooks, M.D., and Robert J. Flemma, M.D. *Yale University:* Lawrence S. Cohen, M.D.,* Rene Langou, M.D., Alexander S. Geha, M.D., Graeme L. Hammond, M.D., and Richard K. Shaw, M.D.

Coordinating center. *University of Washington:* Lloyd D. Fisher, Ph.D.,* Mary Jo Gillespie, M.S., Kathryn Davis, Ph.D., J. Ward Kennedy, M.D., Richard Kronmal, Ph.D., and Charles Maynard, M.A.

Chairman of steering committee. Thomas Killip, M.D., *Henry Ford Hospital.*

National Heart, Lung, and Blood Institute. Peter Frommer, M.D., Deputy Director, and Michael Mock, M.D., Chief, Cardiac Diseases Branch.

*Principal Investigator.

Appendix

1. Estimated probability of in-hospital mortality. Stepwise linear discriminant analysis estimates the probability of OM as a function of individual patient characteristics. An estimation of OM for an individual patient undergoing isolated CABG can be derived for a predictive model using age, LV score, LVEDP, and the presence or absence of LMCD ≥90%. The formula is applied in the following manner. Suppose on an individual one measures the following four variables:

$$x_1 = \begin{cases} 1 \text{ if the LMCD is } \geq 90\% \\ 0 \text{ if the LMCD is } < 90\% \end{cases}$$

x_2 = the LV score as described in the text
x_3 = the LVEDP
x_4 = age in years

The linear discriminant analysis estimates the probability of surgical mortality by an equation of the form,

$$\frac{\exp(c + b_1x_1 + b_2x_2 + b_3x_3 + b_4x_4)}{(1 + \exp(c + b_1x_1 + \ldots + b_4x_4))}$$

Here "exp" is the exponential function of the quantity in parentheses. The exponential function raises the number 2.71828+ to the power of the number in brackets. The coefficients estimated from the data set are as follows:

	Males	*Females*
c	−9.462	−6.964
b_1	2.716	2.946
b_2	0.122	0.0508
b_3	0.036	0.0602
b_4	0.0649	0.04106

Consider a 50-year-old man undergoing an isolated bypass operation. Suppose the left ventricle is normal (LV

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Table A. *Estimated probability of operative mortality for men and women having isolated CABG*

Age (yr)	LV score	Percent operative mortality for men						Percent operative mortality for women					
		LMCD < 90% LVEDP (mm Hg)			LMCD ≥ 90% LVEDP (mm Hg)			LMCD < 90% LVEDP (mm Hg)			LMCD ≥ 90% LVEDP (mm Hg)		
		12	18	25	12	18	25	12	18	25	12	18	25
35	5	0.2	0.3	0.3	3.1	3.9	4.9	1.0	1.5	2.3	16.7	22.4	30.5
	12	0.5	0.6	0.8	7.1	8.6	10.8	1.5	2.1	3.2	22.3	29.2	38.5
	18	1.0	1.3	1.6	13.6	16.4	20.1	2.0	2.8	4.3	28.0	35.8	46.0
50	5	0.6	0.7	0.9	7.9	9.6	12.0	1.9	2.7	4.1	27.1	34.8	44.9
	12	1.3	1.6	2.1	16.7	20.0	24.3	2.7	3.8	5.7	34.7	43.2	53.7
	18	2.7	3.3	4.2	29.5	34.1	40.0	3.6	5.1	7.6	41.9	50.8	61.2
65	5	1.5	1.8	2.3	18.5	22.9	26.6	3.5	4.9	7.3	40.8	49.7	58.5
	12	3.4	4.2	5.3	34.7	39.8	45.9	4.9	6.9	10.1	49.6	58.5	68.2
	18	6.8	8.3	10.5	52.5	57.9	63.8	6.5	9.1	13.3	57.1	65.7	74.5
75	5	2.8	3.4	4.4	30.2	35.0	40.9	5.2	7.3	10.7	51.0	59.8	69.4
	12	6.3	7.7	9.7	50.4	55.8	61.9	7.2	10.0	14.5	59.7	68.0	76.4
	18	12.3	14.8	18.3	67.9	72.4	77.2	9.5	13.2	18.8	66.8	74.3	81.5

Legend: CABG, Coronary artery bypass grafting. LV, Left ventricular. LMCD, Left main coronary disease (stenosis). LVEDP, Left ventricular end-diastolic pressure.

Table B

Variable	Codes	Coefficient, b_i
Age	In years	0.05037
LV score	Described in text	0.11504
Sex	1: Male 2: Female	1.10688
LMCD	0: <90% Stenosis 1: ≥90% Stenosis	2.61236
Rales	1: Present 0: Absent	−1.59576
CHA anginal class	0: No "anginal" chest pain 1 through 4: Classes I through IV 5: Unrelated to exertion	0.16473
Constant (C)		−6.59490

Legend: LV, Left ventricular. LMCD, Left main coronary disease. CHA, Canadian Heart Association.

score = 5), there is 15% LMCD, and the LVEDP is 18. What is the estimated surgical risk? Using the formulas:

$$\exp(c + b_1x_1 + \ldots + b_4x_4) =$$
$$\exp(-9.462 + 2.716 \times 0 + 0.122 \times 5 + 0.036 \times 18 + 0.0649 \times 50) =$$
$$\exp(-4.959) = 0.00702$$

$$\text{Probability of surgical death} = \frac{0.00702}{1.00 + 0.00702} = 0.0070$$

Table A gives the estimated probability of surgical death for various combinations of these four variables.

2. Expected number of deaths at a clinic. The linear discriminant analysis gives an estimated probability of death for each patient. The average or expected number of deaths at a site is estimated by summing the estimated probability of in-hospital mortality for each case. A site with high-risk patients will have a higher estimated number of deaths than a site with low-risk patients and the same number of operations. The variables used for the estimated probability and the values of the coefficients are given in Table B. The expected number of surgical deaths were used for the adjustment discussed in the text.

Discussion

DR. CHARLES H. MOORE
Beaumont, Texas

The CASS report offers a rare combination of large numbers of coronary patients treated surgically and meticulous quality control of data acquisition at multiple institutions. The multivariate discriminant function for the logistical equation developed by the authors and used for comparison of risk factors has been used to compare the surgical efforts of the several institutions. I am sure we would all like to see the actual equation with its coefficients so that we could check our own statistics.

Last year we presented our risk factor data on 434 patients using a univariate analysis related to mortality. We evaluated preoperative variables, clinical descriptors, hemodynamic data, and operative variables, and we ranked in order of significance factors similar to those presented in this report, with the measure of left ventricular dysfunction having the most significant predictive power of mortality with univariate analysis.

With the univariate analysis the interrelationship of various

factors is uncertain and our numbers were too small to generate significant multivariate discriminant analysis.

Our conclusions were limited to being able to rank the number of risk factors as they relate to mortality in a linear fashion. The various weights could not be assigned for each particular risk.

Female sex was not a risk in our series, and this has emerged clearly as an important risk of operative mortality (OM). The CASS study has enough data and patients to provide clear identification of the female sex as a risk when multiple variables are included.

This important presentation of CASS data will become the gold standard by which many of us can measure our own performance in our own institutions.

I would like to ask Dr. Kennedy about the ratio of observed to expected mortality (O/E ratio) in their efforts to standardize results from the various institutions. Specifically, what is the standard area of measurement of this ratio and what is the level of confidence? For example, if site 1 has a ratio of 0.3 and site 2 has a ratio of 0.6, what is the probability of this occurring by chance?

Second, I would like to ask if a definite discriminant analysis of risk factors was performed at each institution and how often the same variables were chosen, in what order, and with what uniformity?

DR. QUENTIN R. STILES

Los Angeles, Calif.

Of what value are these data to the cardiac surgeon and the public?

To summarize, these are the operative mortality (OM) figures from an unselected cooperative, prospective, 3 year study from fifteen institutions involving over 6,000 patients. Many surgical teams contributed, and because of the institutions involved this report represents the first-class surgical management of coronary artery disease. It should serve as a base score for comparison and evaluation by others.

The most striking figures are the differences in OM between institutions. Site 15 had an OM 22 times that of site 1. Did hospital 15 do more high-risk cases? Using the multivariate discriminant analysis approach to compensate for this arriving at an O/E ratio, however, the discrepancy actually became worse. The mortality of institution 15 was then 30 times greater.

About 10 years ago, when the regional medical programs were in vogue, I was asked to chair a committee to report on cardiac surgery in our Los Angeles area, mainly regarding OM. The variations among our institutions were enormous. Los Angeles at that time had 33 hospitals doing cardiac surgery and the mortality figures ranged from 5% in the two hospitals doing the highest volume up to 40% in one and over 50% in another hospital, both doing moderate amounts of cardiac surgery.

What has happened since then? There still are more than 30 institutions in Los Angeles where cardiac surgery is performed. The two with the flagrant results are still in business and still having their problems.

Why do hospitals continue with heart surgery when results are unacceptable? Ego, prestige, and financial rewards are sometimes more important than patient care. Also, high mortality rates are not always apparent even to those working within such institutions. Why is it so difficult to obtain comparative OM rates for any type of operation between hospitals? The public deserves to have this information because, if it became widely known, these vast differences in mortality would not persist for long.

DR. ELLIS JONES

Atlanta, Ga.

We recently have reported on the relationship of certain clinical, anatomic, and functional descriptors and surgical mortality following the coronary bypass operation in 3,400 consecutive patients at Emory University Hospital. The CASS report carries this analysis one step further by using the multivariate discriminant analytic technique. Results of this study are similar to our own, but there were a few differences.

First, advanced age (≥70 years) in our series was predictive of a higher OM. The OM was 2.0% for patients ≥70 years compared with 1.4% for patients less than this age. In our own series, there has been no significant difference in OM on the basis of sex. Left main coronary artery disease (LMCD) was predictive of a higher OM, particularly when left ventricular dysfunction was present (2.6% for patients with LMCD and normal left ventricular function and almost double, 4.3%, for those with left ventricular dysfunction).

Elevated resting left ventricular end-diastolic pressure (LVEDP) was associated with a higher OM only when this value equaled or exceeded 20 mm Hg. At this level it usually was a manifestation of severe left ventricular dysfunction. In our own patients, ejection fraction proved a more reliable predictor of OM than angiographic abnormalities of segmental wall motion. For ejection fractions in the low range, less than 0.25, OM in our hands was 4.2%. In the intermediate range (0.25 to 0.49) it was a 2.1%, and if ejection fraction was normal (>0.49), OM was 1.2%.

A stable or unstable anginal pattern did not significantly affect hospital mortality. If hypertension was present, however, hospital mortality was greater (2.2%, compared with 1% if hypertension was not present). This finding is probably related to a large ventricular muscle mass with poor myocardial preservation.

If there was no previous history of myocardial infarction, hospital mortality was 1%; if the patient had had one infarction, it was 1.8%; and if the patient had a history of multiple infarctions, the OM was 2.2%.

If heart failure was present, hospital mortality was 4%, as opposed to 1% if there was no history of heart failure.

In the past 3 years, a time period somewhat analogous to the time sequence of the present study, our overall hospital mortality has been 0.8%.

In conclusion, excellent OM figures are now attainable, as demonstrated by the overall OM of 0.3% of one of the participating institutions. Furthermore, five of the participating institutions had an OM ≤1%.

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Speaking as a surgeon, I am pleased to see cardiologists participating in this type of study. They must surely recognize that many of the clinical variables elucidated in this report and our report are the direct result of progressive left ventricular damage caused in many cases by procrastination and prolonged medical therapy. The best operative results and long-time survival will be seen in patients who do not have such manifestations of myocardial damage.

I have one question, which alludes to those factors mentioned by Dr. Stiles. Do you have any results from this multivariate analysis that would give us some insight as to why OM is greater in women, why it is higher in older patients, and why it is more severe in patients with critical left main stenosis?

DR. KENNEDY *(Closing)*

Thank you, Dr. Moore, Dr. Stiles, and Dr. Jones, for commenting on our paper.

Dr. Moore asked for the confidence limits for the O/E ratio. The ratio is derived for each site by estimating the OM for each patient at each site using the predictive model. These estimated risks are then combined to derive an estimated OM for the institution as a whole. The O/E ratio is then derived for each site. To our knowledge, there is not an accepted method for deriving confidence intervals for this technique. The methodology needs to be developed.

Dr. Moore also asked if multivariate analysis has been done site by site as well as for the total group. We have not done this since it was our aim to compare the performance at each site with performance of the group as a whole. The results would likely be quite variable from site to site since the OM and O/E ratio varied widely between institutions.

Dr. Stiles and Dr. Jones both asked me to comment on the reasons for increased mortality in women and the wide variations in OM between institutions.

I do not know the reason for increased OM in women. Some of my surgical colleagues have attributed this increased mortality to smaller caliber coronary arteries and the smaller size of the heart in women. We are very interested in these findings and plan to do further analysis of our data to see if we can explain the higher OM in women.

Why is there such a large difference in OM among the 15 CASS sites? One of the main objectives in this data analysis has been the evaluation of OM relative to the particular patient populations at each institution. We have shown that the patient population accounts for increased or decreased OM at only a few sites. The remaining variation in OM must be related to other factors. I believe that there must be very significant differences in surgical expertise from site to site to account for these enormous differences in OM.

CHIEF MEDICAL DIRECTOR'S STATEMENT ON
MIAMI VA MEDICAL CENTER'S CARDIAC SURGERY PROGRAM

The cardiac surgery program at the Veterans Administration Medical Center (VAMC) in Miami was suspended because of community concerns incident to news accounts about high mortality rates in the past.

A team of eminent cardiac surgeons from outside VA was appointed to review the program. The professional excellence of the three surgeons on this team is reflected by the fact that each is currently a professor of cardiac surgery at a major U.S. medical school, each has served as president of the American Association of Thoracic Surgery, and all hold numerous other prestigious professional credentials.

They began their investigation with a meeting in VA Central Office, in Washington, DC, on January 3, 1985, at which the members reviewed material provided by staff members from the University of Miami Medical School and the Miami VAMC. The team reconvened in Miami on January 15, where they reviewed additional patient documents, facilities, staff credentials and interviewed various VAMC and University staff members.

The team has reviewed the past history of the Miami program including the personalities involved, the relationships with the University and the morbidity/mortality statistics. They reviewed in depth the recent performance and present state of the program. They reviewed in detail case histories of patients operated on by the present cardiac surgery team. They assessed the improvement of support and physical facilities that has taken place since 1980, including a new surgical intensive care ward and new equipment and considered the enthusiasm of the nursing and support staff in the intensive care unit.

In reviewing the case histories of patients who died, they reviewed the quality of the workup, cardiac catheterization data, angiograms, and procedures for monitoring patients postoperatively for appropriateness. The team compared mortality rates at other Miami institutions with that of the Miami VAMC. They evaluated whether administrative problems affected the quality of this cardiac surgery program.

As a result of the team visit I have concluded that:

1. There is a need for a VA cardiac surgery program in the Miami area. The Miami VAMC is ideally suited to meet this need, and the program already established in the VAMC for cardiac surgery should be resumed.

2. The general VA requirement for a minimum number of operations should be relaxed in view of the close affiliation with the University and overlapping of the surgical staff and the surgeon and pump team since they have responsibilities in both places.

3. The clinical work performed by the Miami cardiac surgery team should be reviewed weekly by the staffs of the VAMC and University, and this process should include prospective review of work planned as well as thorough review, within a week, of morbidity and mortality.

4. The present chief of the VA cardiac surgical program is to be encouraged to continue his leadership of the VA program and to participate part time as a member of the cardiac surgery program at the University.

5. The ratio of nurses to patients should be reviewed locally and by VA Central Office;

6. The program should be externally reviewed again within one year.

Based upon the foregoing, I have directed that the cardiac surgery program at the Miami VAMC be reopened as soon as possible, with appropriate attention to the matters I have outlined. I have, in addition, advised the Miami facility that I wish to pay special tribute to Dr. Lancelot Lester, chief of the cardiac surgery unit, for the progress he has brought to this important program.

JOHN W. DITZLER, M.D.
Feb. 15, 1985

Office of Public
and Consumer Affairs

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Veterans Administration

News Release

FOR IMMEDIATE RELEASE

VA REOPENS MIAMI MEDICAL CENTER'S CARDIAC SURGERY PROGRAM

The Veterans Administration has announced it will resume the cardiac surgery program at the Miami VA Medical Center that was suspended last December pending an independent review. VA Chief Medical Director Dr. John W. Ditzler concluded that the team visit confirms that the quality of the specialized surgical unit clearly meets agency criteria.

A three-physician team of eminent cardiac surgeons from outside government conducted the investigation following allegations that the Miami program was poorly regulated and had excessive mortality rates. Ditzler suspended the program to alleviate concerns by patients while the unit's activities were being scrutinized. Other VA facilities handled cases during the two-month suspension.

In reopening the program, Ditzler said, "I believe this whole process will serve as a vote of confidence for the Miami program. Veterans and their families can be reassured that their present and future needs will be met skillfully and with utmost concern for the quality of their care."

Ditzler also said he would implement the following actions:

* Relax the requirements to maintain a minimum number of procedures within the VA unit since close affiliation with the University of Miami affords adequate staff activity.

-more-

- Require that all clinical work prior to and following surgery be reviewed by a joint VA-University team on a weekly basis.
- Re-examine current nurse-patient ratios throughout the medical center.
- Conduct another external review of the Miami program within one year.

Ditzler confirmed that he was moving forward with an agencywide examination of cardiac care at all VA facilities. He said the broader review would be conducted by an 11-member panel of expert physicians from outside the agency with expertise in cardiology, cardiothoracic surgery and medical ethics.

The Miami report was prepared under provisions of VA's medical quality assurance statute which provides confidentiality for the review. The team report, however, has been released to both the Senate and House Committees on Veterans' Affairs in their oversight capacity of VA programs.

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FEB 15 1985

STATEMENT OF GERARD A. KAISER, M.D.

Committee on Veteran's Affairs

Subcommittee on Hospitals and health care of the U.S. House of Representatives

I hold several positions at the University of Miami School of Medicine and I appear before you today prepared to discuss how each of these roles interface with the question before us namely the Cardiac Surgical Unit at the Veteran's Administration Medical Center in Miami. First, in my capacity as Deputy Dean for Clinical Affairs of the School of Medicine. As I know you are aware, the relationship between the School of Medicine and the Veteran's Administration Hospital goes back to the beginnings of the Medical School in 1952. We are a Dean's Committee Hospital and I assure you that the relationship between the Veteran's Administration Hospital and the School of Medicine is very close and we look on the hospital and its staff as an integral part of the School of Medicine. Over the past several years we have established several uniques Programs in which the roughly one hundred physicians on the staff of the Veteran's Hospital and the faculty of the School of Medicine have in essence achieved equity with those faculty members who are not on the staff at the Veteran's Administration Hospital in regard to their fringe benefits and retirement program. This Program is at cost in University Department dollars in order to assure that faculty at the School of Medicine are treated in the uniform manner. As you know, the hospital is located across the street from the medical school and the University of Miami/Jackson Medical Center which is the other teaching hospital in our medical center complex. The Veteran's Administration Hospital its staff and physicians, therefore, play an important role in the medical school in both medical student education and postgraduate residency training.

I also serve as a Professor of Surgery and Chief of the Division of Thoracic and Cardiovascular Surgery and consultant in Cardiac Surgery to the Veteran's Administration Hospital. The Section of Cardiothoracic Surgery at the Veteran's Administration Hospital was established in 1972 with funding for two full time equivalent staff positions and the designation of the rotation at the Veteran's Administration Hospital as a six month component in the second or senior year of our formal two year residency training program. From its inception to the present, this Program has continued unchanged with the Veteran's Administration Hospital rotation comprising in quarter of the residency training program which has provided experience in Thoracic, Cardiac, and Pacemaker Surgery, and recently Esophageal Surgery for the Thoracic Surgical Residency trainee.

The commitment of our faculty to the VAH has, from the beginning, required one or more faculty be assigned to that facility for a major portion of his clinical duties. In the past twelve years there have been several changes in our faculty as can happen in an Academic Program. I will give these changes in detail shortly. Also during the past decade, there have been several changes in the leadership of the Cardiology Service, and intervals when there was no full time Chief of Cardiology nor Director of the Catheterization Laboratory as will be discussed by Dr. Myerburg.

During the same period, the Cardiac Surgical Program has developed during a time when it was necessary to obtain funding from the hospital for ancillary personnel, facility improvement, and equipment and perfusionist support from a budget in which there were no funds assigned for Cardiac Surgery.

This problem has been resolved within the past year and has allowed us to establish a program where the perfusionists under contract are the same as those used at University of Miami/Jackson Medical Center and there has been the ability to assign beds in the Intensive Care Unit as well as the Stepdown Unit to be used by the Cardiac Surgical Patients.

The Cardiac Surgical staff support VA Hospital has been as follows:

1970-78: Surgery was performed mainly by Drs. Thurer and Vargas. Dr. Thurer initially headed the Unit and was succeeded by Dr. Vargas in 1979. Dr. Vargas left the VA Hospital staff and the University to enter private
1980 practice in Miami and was succeeded by Dr. Frederick Wideman, in 1980. Dr. Wideman had been in practice for seven years and then spent two years at the University of Alabama School of Medicine doing clinical and basic research. It appeared that his background in clinical surgery and maturity would fit well into the needs of the VAH. During 1980, because of an unacceptable high mortality rate possibly associated with questions of equipment failure, and inadequate support personnel, the Program was voluntarily suspended as these problems were investigated. Dr. Wideman was relieved of his duties at the VAH and was replaced by Dr. Innes in November of 1981. During the four months he stayed at the Institution and on the faculty, he had an exemplary record and not a single patient death. He left in January 1982 when he became ill. His illness was the development of an active bleeding ulcer which he felt was in part caused by the tension and strain of functioning within the VAH setting where pressures for performance in light of the severity

of illness, acuity of the patients, and the overall conditions yielded a patient population which would be of higher risk than the unusual cardiac surgical practice.

Dr. Innes left precipitiously and attempts to secure a replacement included extensive negotiations with the Chief at the VA Hospital associated with Harvard and the Peter Brent Brigham Hospital in Boston, also the Chief at the Asheville (Oteen) VA Hospital, and others including several members of the staff at the Baylor University Medical Center. In the interim, surgery performed at that Institution was covered on a case need basis on rotation by members of the staff whose primary
1982 responsibility was at Jackson Memorial Hospital. In August 1982, Dr. Alex Zakharia, Board Certified in General Surgery and Thoracic and Cardiovascular Surgery, and a graduate of the University of Miami Program in the late 60's, was appointed as Acting Chief of the Section. His responsibilities were to supervise the teaching program, and resident education, and to reinstate the cardiac surgical program with a full time presence at the VA Hospital. He stayed in that capacity until a permanent replacement could be recruited. This was accomplished when
1984 Dr. Lester was recruited from Henry Ford Hospital. Dr. Lester completed his general surgical training at the University of Miami School of Medicine, was Director of the Trauma Service at this Institution before taking his cardiac and thoracic surgical training at Emory University Program. Following his completion of that Program, he spent a year at the Cleveland Clinic and then became a staff surgeon at Henry Ford Hospital, Detroit. I felt that Dr. Lester's previous knowledge of the University, its relationship to the VAH, and the importance of this program within

the Division of Thoracic and Cardiovascular Surgery, including supplemental financial support, would supply the expertise and leadership required to provide excellent clinical and operative results. Dr. Lester has performed in an outstanding fashion by dint of his personal commitment and effort to this Program. His results have been analysed by the external review committee and his skills have been duly noted. I must add, however, that I believe it is difficult for both the patients and physicians to interact and proper patient care be delivered when each is under continuing scrutiny by the media.

This set of circumstances can severely restrict the therapeutic options available to the patient and his physicians as high risk procedures are not performed because of the publicity surrounding results. We participate in a strict Peer Review Process, Quality Assurance Program and welcome Central VA Administration or non-VA physician review of our performance.

I hope that the report of this Committee based on this investigation and all the material available to you will establish the fact that this Program is one of quality care and commitment on the part of the involved physicians to the patient population which we serve in South Florida. This patient population continues to grow, and also to increase in the percentage of those over age 65. We recognize our obligations to this group and wish to provide the finest care to these patients. We believe this care is comparable to that which is available at the other hospitals in South Florida, in which cardiac surgery is performed. Thank you for the opportunity to make this presentation and I will be happy to answer any questions concerning this material.

PREPARED STATEMENT OF ROBERT J. MYERBURG, M.D.

The Division of Cardiology at the University of Miami Medical Center is responsible for clinical, educational, and research activities at 3 sites: (1) 2 large hospitals, Jackson Memorial Hospital and the Veterans Administration Medical Center; (2) a small private facility, the University of Miami Hospital & Clinics (NCCH). The Division of Cardiology is organized as a single unit for administrative, policy-making, and educational purposes, and all physicians at each of the hospitals are full-time faculty members of the University of Miami School of Medicine.

The only functional separation between the 2 large facilities, Jackson Memorial Hospital and the VA Medical Center, is the need to maintain a faculty primarily assigned to each of the two institutions for day-to-day clinical activities. The nature of cardiovascular disease requires that identified individual physicians be assigned to intensive cardiac care and other special functions within our discipline for proper continuity of care.

I have first-hand knowledge of VA Medical Center operations, since I was initially recruited to Miami as Chief of the Cardiology Section at the VA Medical Center in 1970, and served in that capacity for approximately 3 years. In 1973, I was appointed Director of the Division of Cardiology for the University of Miami Medical Center which, as I indicated earlier, encompasses the VA program. When I left day-to-day operational responsibilities at the VA in 1973, 4 full-time faculty members were assigned to that facility to maintain the clinical activities.

Dr. Kaiser came to the University of Miami as Chief of Cardiovascular and Thoracic Surgery in 1971. We had known each other during our tenure at Columbia University, and upon his arrival agreed that we would maintain a functional interaction between the cardiology and cardiovascular surgical programs. Dr. Kaiser's policy has been to provide a surgeon whose primary responsibility would be to the VA surgical program. Throughout the years since then, as is common in many academic institutions, times of faculty turnover in both the Division of Cardiology and the Division of Cardiovascular and Thoracic Surgery have caused transient periods of

destabilization in the clinical services at the VA. It was just such an occurrence in 1980, for instance, that caused a temporary voluntary closure of the surgical program by Dr. Kaiser at that time. At the same time, we had temporary faculty in the cardiology division while we were awaiting the ability to recruit a permanent Chief, this being contingent upon recruiting a permanent Chairman of the Department of Medicine for the University of Miami. The recruiting efforts for both the Chairman of Medicine position and VA Chief of Cardiology position were successfully completed within the next year or so, and since then we have had a full complement of cardiology faculty in support of the clinical needs of the hospital, plus medical support for the surgical program. A change in leadership was made recently, in response to problems solely related to administrative circumstances, but at present the Cardiology Section still consists of 4 faculty members, covering all aspects of modern cardiology. These include, but are not limited to, intensive cardiac care, cardiac catheterization, stress testing, echocardiography and electrocardiography and Holter monitoring.

As a consequence of these successful recruiting efforts in the Department of Medicine, Dr. Kaiser was then able to recruit Dr. Lance Lester to direct the cardiac surgical program at the VA Medical Center, and he joined our faculty on January 1, 1984. Dr. Lester has integrated well into the team concept of the medical-surgical relationships, and developed mutual respect and confidence with the cardiology group.

Dr. Kaiser has summarized the total surgical experience at the VAMC since Dr. Lester's arrival. In addition, I would like to point out that, from the perspective of the Division of Cardiology, several factors must be taken into consideration. First, the patient population that we deal with at the VA Medical Center in Miami is generally older, has more advanced heart disease, and is a higher risk category among surgical patients. Despite this, there have been only 4 deaths among 60 surgical procedures in the last 6 months, 3 of which occurred in the course of emergency surgery which carries an intrinsically higher risk, and only one of which occurred during elective surgery. All of the deaths that have occurred since Dr. Lester's arrival

were analyzed by the group of 3 eminent surgeons sent by VA Central Office in January, 1985 to evaluate the program. I understand that their report is available to you. I would like to point out, however, that from the point of view of the medical cardiologists involved in the VA program, and my own personal supervisory function over that component of our program, I am satisifed that any deaths which have occurred were not outside of the range of acceptable standards of surgical risk, and that in fact Dr. Lester is an excellent surgeon, both in terms of his technical skills and his operative and post-operative judgment. The Division of Cardiology is fully supportive of this aspect of our program, of the surgical service being provided to the VA patients, and of the attitude and cooperativeness of Dr. Lester and other members of the surgical department. Furthermore, I believe we are now in a position to move ahead with a clinical cardiology and cardiovascular surgery program at our Veterans Administration Medical Center which can provide the highest level of clinical service to the south Florida veteran population which we serve.

I should also point out the importance of maintaining a cardiac surgical program in our VAMC in Miami. Dr. Lester has (or will) outline the magnitude of the veteran population we serve. The cost efficiency and convenience to our veterans of maintaining this program is self-evident. Less obvious, but even more important, is the need for a surgical program to maintain an excellent medical cardiology program. Modern cardiology is intimately related to cardiovascular surgery. Medical cardiology without surgical support in a hospital the size of the Miami VAMC serving such a large population would be an undesirable setting for bright and talented cardiologists. I believe that our ability to maintain a strong VA faculty is dependent upon the continued presence of surgical support.

I will be pleased to answer any questions that the committee members may have.

STATEMENT OF

JOHN W. DITZLER, M.D.

CHIEF MEDICAL DIRECTOR

DEPARTMENT OF MEDICINE AND SURGERY

VETERANS ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON HOSPITALS AND HEALTH CARE

COMMITTEE ON VETERANS' AFFAIRS

HOUSE OF REPRESENTATIVES

March 21, 1985

Mr. Chairman and Members of the Subcommittee:

I am pleased to appear before the Subcommittee to discuss the VA cardiac surgery program and more specifically the program at the VA Medical Center in Miami, Florida.

The VA cardiac surgery program was officially established in 1964 with thirteen funded sites. Today there are forty-three in-house programs and seven university contract programs. To assure excellence in this complicated highly technical tertiary type of patient care program, a Consultants' Committee was established in 1971 to monitor the quality of care and make programmatic recommendations to Central Office officials. This group has met every six months to review relevant material, conduct audits, and recommend program sites. Cardiac surgery is the most closely monitored VA surgical program. Only one other comparable group of cardiac surgery programs, in New York state, is as closely monitored. For this and other reasons, the overall mortality rate of open heart surgery has

been reduced from 16% in 1969 to 5% in 1979, and 4.7% in 1984. In the same time frame, the total number of cases which include valve replacements and coronary artery bypass cases has increased from 637 in Fiscal Year 1969 to 6,450 in Fiscal Year 1984.

The VA mortality rate exceeded the rate for the civilian community in the early 1970's, however, today it is roughly equivalent. Credit for this reduction of mortality has to be given to improved technology, accumulation of experience, and close surveillance of the program. It should be noted that VA mortality statistics and non-VA mortality statistics are frequently not comparable. Some private sector reports define mortality as only that which occurs in the operating room at the time of surgery. The VA mortality statistics include those cases that died in the operating room, plus the cases that died for any reason within thirty days of surgery, and in addition, any cases in which death occurred more than thirty days after surgery but was as a result of a complication that was first manifested within thirty days following surgery. Some private sector reports tabulate the mortality for coronary artery bypass procedures only and do not include the mortality for heart valve replacement procedures; the VA statistics include both types of procedures. The mortality rate for valve replacements is always much higher than that for coronary bypass procedures.

The Cardiac Surgery Consultants Committee, which is made up of a combination of VA and non-VA cardiac surgeons and cardiologists, has established criteria for program review which Central Office officials have adopted. These criteria

include a volume of at least 100 cases per year. It is felt that this workload is necessary to maintain professional skills of all cardiac surgery treatment team members. If the mortality for any six month period exceeds twice the VA overall average, each death case is audited by a member of the Consultants Committee and presented to and discussed by the entire Committee. The results of these audits and recommendations of the committee are then returned to the responsible program chief for comment and appropriate follow-up action.

In the past six years, seven programs have been closed due to insufficient volume, a combination of insufficient volume and high mortality, or excessive costs. Two of these programs were in-house and five were contracts with universities. From 1969 through 1984, over 65,000 open heart cases have been performed in VA programs.

Review of audits of deaths in a nationwide cooperative study revealed that the most common cause of death was the advanced stage of the patients' disease. The VA operates on some higher risk patients as a last resort emergency life saving procedure and on others referred to the VA after having been denied surgery elsewhere in the private sector. Many of these patients are elderly and/or have multi-organ system disease. After being informed of all the risks, patients insist that they would rather risk surgery than live with their pain or disability.

The cardiac surgery program at the Miami VA Medical Center was first authorized and funded in Fiscal Year 1968. Letters of caution about volume requirements were sent in 1971, 1978, 1981, 1982, and 1983. Their fatal cases were audited in 1972, 1977, 1980, and 1983. On each occasion, the results of the audits were discussed by the consulting committee and conclusions were then returned to the program official at Miami. For example, in 1980, a site visit was recommended. However, since the station, on its own accord, stopped the program, hired a new surgeon, retrained the surgical team, obtained a new pump technician and bought a more modern heart-lung machine, the site visit was cancelled. It was the consensus that every action that a site visitor might have recommended, was accomplished by the station, making a visit unnecessary. In 1983, a letter of warning was sent to the Miami facility, and a site visit was conducted in May 1984. Since a fully qualified cardiac surgeon was hired in January 1984 and there was evidence of much improvement, the program was continued.

In December 1984, a series of articles was published in Florida newspapers. Allegations of excessive mortality in the cardiac surgery division of the Miami VA Medical Center were reported. Such publicity results in understandable anxiety among candidates for surgery and increases risk. Therefore, I temporarily closed the program pending review by a team of eminent cardiac surgeons. The team first met in early January in Central Office where material available concerning our overall program as well as the Miami program was reviewed. Additional material was also presented to the team members by officials from the Miami VA Medical Center and the affiliated university. The team later visited

the Miami facility where additional case records and the facilities were reviewed and discussions held with the personnel involved. The review team examined the quality of the medical workup of all patients, cardiac catheterization data, angiograms, and the procedures for monitoring patients post-operatively. They also examined the facilities and assessed the morale of the staff. The status of the equipment was evaluated. The team compared mortality rates at other Miami institutions with that of the Miami VA Medical Center. They reviewed in detail the case histories of those patients who died and considered the high risk factors associated with these and the other cardiac surgery patients.

Based upon the review made by the visiting team and other considerations related to the Miami program, I have concluded that:

- The Miami cardiac surgery program should be continued because it clearly meets agency quality standards. Veterans and their families can be reassured that their present and future needs for cardiac surgery will be met skillfully and with the utmost concern for the quality of the services provided.

- VA standards on the maximum number of cases should be relaxed since the close affiliation with the University of Miami affords adequate staff activity.

- Clinical work should be reviewed weekly by the staff, including that of the University, to include prospective review of work planned as well as thorough review of morbidity and mortality.

- High risk patients and activities should be carefully reviewed and shared by the University staff.

- Dr. Lester, the present cardiac surgeon, should be encouraged to continue his work at the VA Medical Center and deserves high praise for his accomplishments in the past year since the program is better now than at any other period of the program's history.

- VA Central Office should review the ratio of nurses to patients, and, if needed, support of the cardiac surgery program should be obtained by shifting personnel.

The site visit report plus a VA Central Office summary of that report were delivered to the Chairman of both the House and Senate Veterans' Affairs Committees. On February 15, 1985, cardiac surgery was reinstituted at the Miami VA Medical Center.

In addition, an agencywide examination of cardiac surgery at all VA facilities has been initiated. A twelve member panel of expert physicians from outside the agency with expertise in cardiology, cardiothoracic surgery, anesthesiology and

medical ethics held their first meeting on Monday, March 18, 1985, here in Washington, D.C. Their mandate is to review and advise on the appropriate numbers and locations of VA programs, what is considered acceptable mortality rates, and the ethics involved, considering high risk factors for surgery and/or anesthesia. I have requested that this group provide a report upon the completion of their deliberations.

Mr. Chairman, I want to assure you and our veteran patients that the quality of services we provide is a top priority of the agency. I believe that the actions taken in this situation and the agencywide review of cardiac surgery programs are examples of this commitment.

We would be pleased to answer any questions which you or other members of the Subcommittee may have concerning the VA cardiac surgery program, generally, or the program at the VA Medical Center in Miami, specifically. However, as you are aware, Mr. Chairman, a VA law (section 3305 of Title 38, U.S. Code) makes records and information derived from a VA medical quality assurance review of a treatment program strictly confidential. For example, the recent team review at the Miami facility was part of this quality assurance process. Consequently, while we were authorized to make the team's report available to the Committee, we were not authorized to make the report public. If in order to fully respond to any of your questions it is necessary to provide information generated by this review process, we will be pleased to supply it to you promptly, in writing.

Thank you for this opportunity to appear before you on this matter.

STATEMENT FOR WASHINGTON HEARING ON CARDIAC SURGERY TO BE HELD ON MARCH 21, 1985
FROM J. LANCELOT LESTER III, M.D.

In 1984 several articles and editorials were published in a Ft. Lauderdale newspaper about the VA Cardiac Program in Miami and elsewhere, in the decade prior to 1984. The articles made the following allegations:

1. The results were poor and could have been better.

2. The responsible individuals failed to perform corrective measures.

3. The volume was low (less than 100 cases per year).

4. The programs should be consolidated to permit concentration of large numbers of patients in a center of excellence with a large experience.

5. Results were much better in comparable private or university centers.

In regard to the first two allegations: The VA officials believed that these results could be improved. They made numerous changes in personnel and equipment over the years including modifying the program, and even halting it. In each case they believe they acted responsibly to improve the program and attempt to maintain services to the large number of veterans in this area.

The third and fourth allegations were of low volume, and the need for consolidation, if necessary to obtain a high volume center, were answered.

The last five and a half months of my tenure we were operating at an annulized rate of 130 patients/year. Starting 6 months prior to my arrival, the number of patients operated upon doubled each 6 months. We were operating on 3-4 patients per week in the months immediately prior to closure. Thus, we would have operated upon more than 150 patients/year during the next 12 months. We believe that within 18 months the Medical Center at Miami would have been operating upon more than 200 patients/year and performing a large number of invasive medical procedures - balloon angioplasty, streptokinase and the attempt to intervene medically to stop heart attacks that were already underway (acute evolving myocardial infarction).

I was recruited to solve the problems of the past decade. My prior experience at the University of Miami and Jackson Memorial Hospital as a Director of the Trauma Service and Surgical Emergency Room, as well as my training at Emory University in cardiac and thoracic surgery was augmented by experience as an Associate Staff Surgeon at the Cleveland Clinic and Attending Staff Surgeon at Henry Ford Hospital.

These qualifications and my assessment of the other staff members' ability led me to believe we could develop a center of excellence based on quality work. My assessment was that:

1. The need was great; a large number of veterans (600,000) lived in the South Florida service area.

2. An excellent volume of 150-200 patients per year could be realized.

3. The staff could support such a program and that further improvements would occur with increasing volume.

4. That the medical leadership was sufficiently mature that they could separate patients by risk category.

5. That many of our patients would be high risk.

6. If we operated upon high risk patients, a higher mortality would result.

7. The most difficult period would be during the early phases when the sickest patients would be most likely to seek and receive care.

8. Results would continue to improve as the volume went up and less ill patients sought and received care.

Having served as a surgeon at different institutions, I have observed that patient populations are very different. Nearly all the patients at the Cleveland Clinic are elective. They appear vigorous and usually are able to maintain moderate levels of activity. Few patients of this type seek and receive care at the VA.

Further, most surgeons quote the mortality for elective coronary artery surgery as "their mortality." As Chief, I have personally calculated mortality in my program. At the VA in the last six months no deaths occurred in patients with elective coronary artery surgery or pure valvular surgery (0% mortality). Only one death occurred in all elective patients in a combined operation for valvular and coronary disease (less than 2%). The overall mortality of 6.6% includes two patients that were operated upon after large acute heart attacks. They had had attempts at angioplasty or streptokinase. In a less aggressive center these procedures would not have been performed.

Further, we obtained the results of four other area hospitals with a similar aggressive approach. The results were similar to those discussed above with no results below 5%.

This evidence of progression of clinical symptoms is central to the evaluation of cardiac surgical programs. Unfortunately, the two large studies, (CASS & VA Cooperative) most often quoted in the discussion of coronary artery patients, were performed upon patients with stable and minimal (CASS) symptamotology. Further, national and international medical centers operate upon people who can, in general, travel to them. Thus, the most critically ill patients are eliminated.

The observed mortality would fall, if patients that could not come to us from another medical center were excluded in the surgical results. The mortality would fall from 4 deaths in 60 patients to 1 death in 57 patients.

Most such national programs are characterized by a high percentage of elective patients with stable symptoms, Class III or less symptoms, absence of diffuse disease of the coronaries, adequate LV function and the absence of recent infarction.

Further, the benefits of surgical over medical treatment are often most apparent in the more seriously ill group. Rigorous pursuit of the lowest surgical mortality by patient selection will deny care to the most desperate patients.

In summary:

1. The articles that were published were about another era.

2. We live in an area of great need.

3. A high volume center of excellence was well on its way when the program was closed.

4. a) The elective coronary and valve mortality was 0% for the last six months.

   b) One death occurred in all the elective group of patients with combined valve and coronary surgery.

   c) The overall mortality of 6.6% is similar to regional hospitals, and includes 3 deaths in patient with heart attacks and intensive care admissions.

The program was closed as many of the targeted goals were reached, and when further improvement could be expected. The veterans expect good care - and the need to prevent past problems from preventing future solutions.

The program was re-opened after a review of the most current results.

I am sure that veterans expect appropriate resources to protect their vital programs.

We are proceeding cautiously after the program reopened. Some high risk patients have been referred elsewhere, within the VA system or other centers.

During the period of closure of the program, 3 high risk patients that could not be transferred elsewhere, were transferred to Jackson Memorial Hospital staffed by the University of Miami.

The current atmosphere of charge and counter-charge diminishes morale and prevents the recruitment of qualified staff. Why work in an institution where high risk patients cannot get care - or if they do, any death makes the program and its personnel suspect?

Mr. Chairman, continued informed media attention to our program will not serve the best interests of veterans of this region. The needless anxiety of patients and relatives and the hospital staff created by this media attention should be put to rest so that we can proceed with our work to provide health care to veterans.

Office of General Counsel Washington D.C. 20420

Veterans Administration

MAY 23 1985

In Reply Refer To: 023

MAY 24 1985

Honorable G. V. (Sonny) Montgomery
Chairman, Committee on Veterans' Affairs
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

Please find enclosed VA's responses to Congressman Gerald Solomon's questions for the record regarding the March 21, 1985, hearing on VA cardiac surgery.

Thank you for giving us this opportunity to reply.

Sincerely yours,

Donald L. Ivers

DONALD L. IVERS
General Counsel

Enclosures

CONGRESSMAN SOLOMON

Question: 1. Why is the VA's Cardiac Surgery Program the most closely monitored program?

Answer: In 1971, it became obvious to VA Central Office officials that cardiac surgery was increasing in volume and was a high risk program. The VA overall average mortality rate then was above the national average. In order to properly monitor the program and identify those programs in the VA that had excessive mortality, a Consultants Committee was appointed whose mandate was to review the VA programs, audit fatal cases when appropriate, and make recommendations to Central Office for correction of deficiencies. They also made site visits and recommended opening or closing programs. Volume and mortality data has been reviewed every six months since 1971. No other VA surgical program has been monitored as long or as closely as has the cardiac surgery program.

Question: 2. You mention that the private sector sometimes measures mortality in ways other than those used by the VA. Do you have any way to compare -- or have you compared -- private hospitals which measure mortality in the same way that the VA measures it?

Answer: The VA definition of surgical mortality for statistical use by the VA Cardiac Surgery Consultants Committee includes all cases requiring the use of a heart-lung machine that died in the operating room, any case that died for any reason within 30 days of surgery, and in addition, any case that died 30 days following surgery but was a result of a complication that was first manifested within 30 days of surgery. Some private hospitals define mortality for coronary artery bypass procedures only and exclude those for valve replacement or

procedures on the great vessels and ventricle. The only published data from private hospitals whose criteria are similar to VA is that compiled by the New York State Department of Health, in Albany, New York. A comparison of VA data with New York data is roughly equivalent for mortality of coronary artery bypass procedures and valve replacements.

Question: 3. You mention on Page 4 of your statement that in 1983 a letter of warning was sent to the Miami VA Hospital. Would you please elaborate on this statement. Why was the letter sent?

Answer: A letter was sent to the Miami VA Medical Center in 1983 warning them that for three years in a row the volume of cases did not meet the criteria of 100 cases, and the mortality was excessive in 1983. Therefore, if an adequate explanation of the mortality and low productivity were not provided, their program would be considered for closure.

Question: 4. Please provide to the Committee the letters of caution, the fatal case audits, the conclusions on the audits, the letter of warning and the site visit report, all referenced at Page 4 of your statement.

Answer: Please see attachments. Copies of the two warning letters, dated 1971 and 1981, and the 1972 audit are not available.

Attachment I - Letters of Warning for 1979, 1982, and 1983

Attachment II - Fatal Case Audits and Conclusions for 1977, 1980, and 1983

Attachment III - May 1984 Site Visit Report

Attachment IV - January 1985 Site Visit Report

NOTE.-Attachments I through IV are retained in Committee files.

Question: 5. Would you please elaborate on how high risk patients should be "shared by the University staff," as you concluded on Page 6 of your statement?

Answer: The intention of this statement is that high risk candidates for cardiac surgery should be discussed jointly by the VA staff with the affiliated University staff so as to obtain second opinions and, therefore, arrive at a concensus regarding operability of individual patients.

Question: 6. Could you tell us if other events of the kind that occurred at the Heart Surgery Unit at Miami have occurred at other locations. If so, what action was taken?

Answer: Other VA medical centers have reported low volume or high mortality in the past, and warning letters have been issued, or audits of fatal cases have been conducted. In most instances, deficiencies have been corrected as indicated by data supplied in subsequent reporting periods. The Miami situation was unique in that the problems extended over a longer period of time and media and Congressional attention caused us to take the action (temporary closure) precipitously until assurances of high quality of care were obtained. In the past, temporary closures have been initiated by local officials while corrective action has been taken. There have never been any Central Office initiated temporary closures except for the Miami program.

Question: 7. Which cardiac surgery programs have been closed? Please provide in writing to the Subcommittee the reasons why each of the seven programs was closed?

Answer:

Cardiac Surgery Program	Date Closed	Reason
Philadelphia, PA	1983	Excessive Contract Costs
Des Moines, IA	1983	Inability to Generate Sufficient Volume
Syracuse, NY	1982	Insufficient Volume and Excessive Contract Costs
Omaha, NE	1982	Loss of Cardiac Surgeon and Difficulty Recruiting Replacement
Jackson, MS	1981	Loss of Cardiac Surgeon and Difficulty Recruiting Replacment
Bronx, NY	1981	Insufficient Volume
St. Louis, MO	1977	Excessive Contract Costs, Low Volume, and High Mortality

Question: 8. Please provide to the Committee a copy of the report when it is made by the twelve member panel of experts. When do you expect it? Who are the members of the panel?

Answer: We will be happy to provide a copy of the report of the twelve member panel when it is available. However, we do not expect a report until the end of 1985. The following is a list of members of the panel:

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Question: 9. Does the law on use of quality assurance documents need changing or modification? Should the VA General Counsel look at this question of release of information to the public or the press in consultation, of course, with you?

Answer: The Veterans Administration medical quality assurance statute, 38 U.S.C. 3305, requires that the Veterans Administration promulgate regulations describing in detail the Health Services Review Organization (HSRO) process and the records and documents made confidential by section 3305. We do not believe that the statute itself requires change or modification. Since the medical quality assurance regulations were published over two years ago, the Department of Medicine and Surgery is currently reviewing and redrafting those regulations in conjunction with the Office of General Counsel.

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